University of Alberta

An In Vitro Analysis of Latex and Non-latex Orthodontic Elastics

by

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A thesis submitted to the faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Masters of Science

in

Orthodontics

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Dedication

This work is dedicated to my wife Nan. Without her support and sacrifice, I would not have been able to pursue and achieve my goals.

Abstract

Two studies were done to assess the force delivery properties of latex and non-latex orthodontic elastics using a system that simulated interarch orthodontic elastic wear. Equivalent non-latex and latex elastics from the same supplier were compared under cyclic and static testing conditions. The latex elastics maintained statistically higher force levels after 8 hours into testing. Cyclic testing caused more force loss than static testing for both types of elastics in the first hour of testing but did not alter the force decay properties of the elastics over the remaining 24 hour testing period. Four different brands of non-latex elastics, of equivalent size and force level, were compared using cyclic testing. The force decay properties were very similar but the ability of the elastics to survive testing was brand dependent. The cross-sectional measurements of the different brands were highly correlated with initial force generation. The initial forces generated by the different brands were all significantly different from the marketed values given by the suppliers and there were some large differences between the brands.

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Chapter 1 - Introduction and Literature Review

1-1 Introduction

Elastomeric materials that are used to apply forces to the teeth and jaws are often used with a limited understanding of the true forces being applied in the mechanical system created. Even if a known force is applied, it is often uncertain what the degradation rate may be over time. The lack of independent research on elastomeric products prior to their usage often means orthodontists are inadvertently testing these products on their patients.

Synthetic (non-latex) orthodontic elastics fall into this category. Since the early 1990's these elastics have been marketed by some of the orthodontic supply companies. Those concerned about the allergenic potential of natural rubber latex (latex) orthodontic elastics are the target market. Without the increasing awareness of latex allergy these products would likely never have been brought into the market place. These products form a relatively small portion of the market for orthodontic elastics but may become more important in the future if latex allergies increase within the orthodontic and dental environment.

The orthodontist needs to know how a material will behave in the oral environment. If a new material behaves differently from our past experience and we are unaware of these differences treatment progress could be impeded or adverse effects could arise.

1-2 Statement of the Problem

The goals of these studies were to determine the force delivery properties of these new elastomeric materials and their predecessors, to better understand the forces being applied to the teeth during treatment and make any adjustments that may be required from what has been done in the past. While these materials have been on the market for some time there is only one published study, that the author is aware of, that has examined the properties of non-latex orthodontic elastics. [1] There are many studies that have looked at the properties of traditional latex orthodontic elastics and these are useful clinical guides for the use of those materials.[2, 3, 4] Few studies have tried to simulate the intraoral interarch usage of orthodontic elastics and no study has done so for non-latex elastics. If an environment could be created that mimics the clinical use of interarch orthodontic elastics it would be of benefit to use this environment to test products that are new and those that have been in use for many years.

1-3 Literature Review

Previously published research has been compiled in this section, beginning with a brief overview of latex allergy and its relevance to the topic. This was followed by a brief overview of the clinical use of orthodontic elastics. The third component of this review was a historical presentation of research on elastomerics (i.e. elastics, chains, modules) in orthodontics. Finally, the recent publication by Russell et. al.[1] on non-latex elastics was reviewed in detail, since it is the only independent research to date on the topic.

1-3-1 Latex Allergy

This research would likely not be necessary if the awareness of hypersensitivity to latex products was not on the rise. Since the mid to late 1980's the number of reported cases of latex anaphylactic reactions has been increasing.[5] The primary sources of latex allergens in the dental field are protective gloves and dental dams. Studies have estimated that latex Type I allergies occur in 4-10% of health care workers and may range from 0.12-6% in the general population. Among dental professionals the number was estimated at 6.2%.[5]

Products are being marketed and sold using non-latex as a marketing tool, although not all of the major orthodontic supply companies have a non-latex product. The demand for these products could increase with an increasing awareness of latex allergy problems regardless of whether or not the latex elastics are a problem themselves.

There was one reported case of an oral mucosal reaction attributed to latex orthodontic elastics in a 1989 survey study by Jacobsen et. al.[6] There are cases of allergic reactions to other latex products in dental offices including one reported case of latex allergy attributed to latex gloves in a patient undergoing orthognathic surgery.[7]

Some of these issues may be irrelevant for orthodontic elastics since their manufacturing process, that involves much higher temperatures which eliminate almost all of the allergenic proteins, is different from latex glove fabrication. Unlike "dipped" latex

products, such as gloves, the "extruded" latex products, such as elastics, may not pose as significant a problem. There is no independent research on the levels of latex protein in orthodontic elastics but marketing information from one source of latex tubing reports "99.99% protein-free" tubing.[8]

The risk posed by latex orthodontic elastics appears to be small since they are widely used and there are few reported adverse effects. However, it would be inadvisable to prescribe standard latex orthodontic elastics to a patient that is known to have a latex allergy of any kind.

1-3-2 Clinical use of Orthodontic Elastics

Elastics are widely used in orthodontics. They may be used within an arch to deliver force to a specific tooth or group of teeth but are more commonly used between arches to deliver directional forces to help correct mild class II and III relationships. They are also used very commonly as cross-bite correcting tools and may be used to reinforce anchorage with space closure or molar distalization. Another common usage is for closure of dental open bites throughout orthodontic treatment. Elastic use in orthodontics has a long history as illustrated by the following:

> "In 1893, Calvin S. Case discussed the use of intermaxillary elastics at the Columbia Dental Congress and certainly Edward Angle described the technique before the New York Institute of Stomatology in 1902." [9]

Early on, stationary elastics were used and were shown as late as the 1970's to be almost as good as those marketed for orthodontic purposes.[10]

The most common use of orthodontic elastics is for Class II correction. Epidemiology studies have found that Class II malocclusions are present in approximately 15% of the population while class III malocclusions are found in approximately 1%.[11, 12] While there are no recent surveys of orthodontic elastic use, extrapolation of this epidemiological data to expect more use of class II interarch mechanics than class III is reasonable. Points of attachment would most likely be the upper canines and the lower first molars.

Interarch elastic wear is prescribed differently among practitioners however many use guidelines similar to those presented in a short clinical publication by Taloumis et. al. [13]. Taloumis et. al. [13] prescribe 24-hour wear of the elastics and ask that the patient change their elastics after every meal and before bedtime.[13] This pattern would go on for 2-3 months or until the desired changes are seen.

One of the desired roles of these elastics is tooth movement. The exact force required to move teeth would depend on the patient and the system being used.[14] Proffit recommended the use of up to 300gm per side with heavy rectangular archwires if there were no extraction spaces. With lighter wires or when spaces are present not more than 150gm of the 300gm per side was recommended.[11] There is no absolute force level since the amount of force that is needed is patient and situation dependent. An average size and strength of elastic may be considered to be ¼'' 4oz (6.35mm, 113gm) but there is no survey of practitioners to corroborate this perception. Individual practitioners will have different sizes and forces of elastics that they will use for different situations and there may be significant interoperator differences.

1-3-3 Previous Research on Orthodontic Elastics and Elastomeric Materials

In 1970 Ware surveyed Australian orthodontists for usage and quality control of orthodontic elastics. The results are now outdated and although the survey did not have a large return, it was interesting to review the results from a historical perspective. One finding was that the majority of elastics were changed after 1-3 days with significant variation among practitioners.[10] There are no more recent surveys but most orthodontists here are taught to advise elastic changes at least once per day. As per Taloumis et. al.[13], an average prescription would ask the patient to change the elastics after meals and before bedtime meaning at least four changes per day.

Andreasen and Bishara [15] compared latex elastics and a brand of synthetic elastomeric chain stretched 65-105mm over three week intervals to study intraarch forces generated. Specific sizes of elastics were tested due to the large range of elastics available. A handheld correx measuring gauge was used and required removal of the elastic from the study environment to measure the force generated. No significant difference was observed, in a pilot study, between a simulated environment with a 37°C water bath and saliva. Initial force decay was most significant in the first hour but the remaining decay after the first day was smaller in comparison.

Another study by these authors examined forces of latex elastics and the same brand of synthetic elastomeric chain when used for class II and III mechanics during a three-week period.[16] 22 and 40 mm were considered as minimum and maximum clinical values

between the cuspid and molar. Testing of the different materials was done in the laboratory in a 37°C water bath. Both latex elastics and synthetic elastomeric chain had force decay however there was less force loss for latex elastics. The 1-day drop in the force levels was 17.2% of initial force for elastics and 54.7% for synthetic elastomeric chain. There was more variability in the batches for the synthetic elastomeric chain compared to the elastics. Testing in this study used a sample of 10 elastics and assumed an "average intermaxillary distance of 28mm".

In 1973, Barrie and Spence [9] performed creep tests on elastics. Creep is a time dependent deformation of a material and may be either dynamic (applied stress is fluctuating) or static (applied stress is constant).[17] This study loaded elastics with a weight and observed the change in length over time and consequent reduction in stiffness. Six elastics were tested per sample as well as products from a number of different manufacturers. The testing environment was a 37°C water bath. Two out of six elastics in each group underwent a cyclic test. This involved cycling the elastic 1cm at 4cycles/minute. Significant differences were seen between the static and cyclic test groups and different elastic sizes. A summary quote from the authors was as follows:

> "Thinner-walled elastics have a long straight portion on their stiffness graphs and the force exerted in the mouth by these bands will be more predictable. Unfortunately the thinner bands also have the larger creep."[9]

Dynamic testing led to significantly more force loss and creep. Informally, suppliers have explained that non-latex elastics are cut thicker to increase the force delivered due to material differences from traditional latex elastics. Barrie and Spence's[9] study suggests that this may increase the variability in forces generated among these elastics. Russell et.

al.[1] observed that some of the non-latex products were thicker than their latex equivalents but this was not the case for both brands tested. The problem with the study by Barrie and Spence[9] was a lack of adequate description of the statistics that were used and a small sample size used for cyclic testing. Another weakness was the lack of adequate simulation model since it only stretched the elastics one centimeter, which was probably not what would be seen clinically. However, this was a significant study since it attempted to investigate the effects of cyclic testing on orthodontic elastics.

A study in 1975 by Hershey et. al.[18] examined the use of synthetic elastomeric chain for tooth movement. A hand gauge was used to measure forces and if there was a discrepancy of greater than 10% between the investigators forces were re-measured. The largest force losses occurred in the first day and on average the elastomers had only 40% of the initial force remaining after 4 weeks. The importance of this study was that it strived for agreement within 10% for its measurements. The study also supported the findings of others that synthetic elastomeric chain has significant force decay over time with extension.

In 1976, Wong [19] examined changes in the forces produced by latex elastics and synthetic elastomeric chains from different sources under dry and wet conditions as well as different stretched distances. Synthetic elastomeric chains were permanently elongated and showed plastic deformation during testing while latex elastics remained more resilient and had a "relative" constant remaining force. Force decay under constant load

showed greatest rate loss before three hours in the water bath. After three hours the force values remained relatively constant over a 21-day period.

> "The forces of mastication and intraoral environment cause natural rubber to break down by formation of knotty tearing mechanisms. The most significant limitation of natural latex is its enormous sensitivity to the effects of ozone or other free radical generating systems such as sunlight or ultraviolet light that produces cracks. The ozone breaks down the unsaturated double bonds at the molecular level as the water molecule is absorbed. This weakens the latex polymer chain. The swelling and staining is due to the filling of the voids in the rubber matrix by fluids and bacteria debris."[19]

The study reported that as soon as 2 to 3 months after manufacturing reduced force levels may be seen from ozone breakdown but no specific tests were shown in the study that related to those conclusions. The author suggested pre-stretching of synthetic elastomeric chain to account for the rapid initial force loss that occurred in those products. This study was a good one for the materials of that time and was a good reference source for material handling. The study supported the need for appropriate storage of these materials in airtight dark spaces and their use within a reasonable time frame.

A very important question when using or investigating orthodontic elastics is the degree of extension required to achieve the desired forces. In 1977 Bales studied this question.[20] The manufacturer's suggested use of orthodontic elastics involves stretching an elastic to 3 times its internal diameter to achieve the marketed force. Bales found that the marketed force was reached at two times internal diameter. A 100% humidity chamber was used to simulate the oral environment and an Instron testing apparatus was used to measure forces. No significant difference was seen between wet and dry states in this study. A study weakness was the sample size. Only five elastics per group were tested, which may have decreased the power of the statistical results.

In 1978, Ash and Nikolai compared force relaxation of synthetic elastomeric chain in vitro and in vivo.[21] This study was one of the more intriguing investigations in this field since it tried to validate the in vitro testing used in materials testing. Fifteen samples per group were tested and forces were measured with a handheld gauge. The gauge measured to 10gm increments. The elastomers tested generated relatively high forces at the extensions tested with approximately 600gm force generated on average with a standard deviation of 100gm. The ability to extrapolate these higher force changes to those that may be more useful intraorally such as 150-300gm may be questionable. The authors concluded that short term in vitro testing was equivalent to in vivo findings while after one week they started to differ significantly.

A later study by Kuster et. al.[22] also studied synthetic elastomeric chain intraorally and in vitro. Force decay was greater in the intraoral tests than in the in vitro tests. However, in vitro tests were done in a dry state. The weakness of the in vitro model limited the comparisons to the study by Ash and Nikolai. One could speculate that in vivo force decay could be greater due to extraneous forces and environmental factors such as pH and enzyme activity.

In 1986 Bertl et. al.[3] studied forces generated by latex orthodontic elastics as a function of time and distance extended in vitro. A simulated environment was used that used saline instead of distilled water. A rapid stiffness decrease was observed in the first 3 hours but limited changes were observed after that up to 8 hours. Continuous extension on boards was used to stretch the elastics and forces were measured with "spring scales".

Four types of elastics were tested and ten elastics were used per group. No dynamic testing was done and no error for the measuring technique was reported.

In 1990 Huget et. al. studied synthetic elastomeric chain.[23] He stated that it was likely that most are polyurethane materials but that the composition was proprietary. Loading and unloading curves were studied after different amounts of time in 37°C water. He described what he felt was happening to the products after they were placed in a water bath. He explained that exposure of synthetic elastomeric chain to water first leads to weakening of intermolecular forces and subsequently to chemical degradation:

> "Specifically, reduction of load requirement after one day and seven days of water storage may be the result of water sorption and the concurrent formation of hydrogen bonds between water molecules and macromolecules. Since leachable substances were not found in one and seven day specimen storage water, it appears that absorbed water functioned initially as a plasticizer, and thereby facilitated slippage of molecules or chain segments past other molecules or segments."[23]

In 1993, Liu et. al. studied latex orthodontic elastics.[4] Two separate tests were performed. First, compliance (strain/stress) testing was done to see if this would give similar results to standard force reduction tests using hand held force gauges. The study also tested the effect of repeat stretching (cyclic testing) on compliance and force reduction. The elastics used were 7.9mm, 170gm elastics and forces were measured at 3cm extension of the internal diameter. Forces were measured at 10sec, 1 min, 3, 5, 24 and 48 hours. Samples of the elastics were cycled from 2-5cm 200, 500 and 1000 times. After the defined number of cycles the elastics were reset to 3cm internal diameter and forces were measured at the same time intervals as the statically tested elastics. The sample size used was five elastics per group and significant differences were observed

between cycled and non-cycled elastics at the 200-cycle level but no significant difference among the cycled groups beyond 200 cycles. The elastics were cycled at a rate of 1cycle/second and references to occlusion texts were used to justify the stretching distances chosen. Liu's study was a good starting point for looking at the effects of repeat stretching of orthodontic elastics and was the only recent study to do so. Repeat stretching was shown to cause 12% more force loss on average when compared to static stretching.

Baty et. al. investigated colored synthetic elastomeric chain.[24] Forces generated along with shape were studied. This study was the only one found that set a statistical percentage difference. A difference in force retention greater than ten percent was considered clinically significant. Statistically and methodologically, this was a good study to compare. Ten percent may be a reasonable difference to use in future studies, however a larger difference may be needed to see a true clinical difference.

Kusy and Stevenson studied synthetic elastomeric chain.[25] Two major mechanisms of force degradation were described, which were elastic stretch and chain slippage with elastic stretch being reversible and the slippage occurring when a load causes a permanent deformation. Different variables (acidity, oxygen content, and temperature) were compared for their effect on force decay and temperature appeared to be the dominant single factor in the degradation of the polyurethane elastomeric material that was tested. Pre-stretching of elastomeric chains was recommended to increase the effectiveness of tooth moving mechanisms using these chains to deliver forces.

Kanchana et. al. published the most recent extensive survey of latex orthodontic elastics in 2000.[2] Elastics from four manufacturers, and of three different sizes, were studied using sample sizes of 15 elastics for the dry tests and 10 elastics for the submerged tests. There were statistically significant differences between comparable sizes of elastics from different manufacturers. Standard force/extension estimates were shown to be inaccurate and in most cases forces were greater at three times internal diameter than marketed force levels. Force decay occurred rapidly and then slowed with an average of 29.9% force lost during the first hour and 32.6% force lost after 24 hours. The authors recommended that a clinician choose a force of 1.3 to 1.6 times that required for a particular extension (they tested multiple extensions) to account for force loss over time. It was noted that changing elastics less frequently might produce more stable force levels over time. Force measurements were done using an Instron testing apparatus but elastics had to be removed from the testing environment to measure forces generated. In addition, no cyclic tests were done. The following statement was made about directions for further research:

> "To gain a more complete and empirical understanding of the physical properties of elastic materials under clinical conditions, it would be useful to include pre-stretching, thermal cycling, using artificial saliva as the immersion medium, and cyclic stretching and relaxation to simulate chewing during the use of orthodontic elastics." [2]

1-3-4 Russell et. al. Study[1]

Russell et. al. tested non-latex orthodontic elastics and compared them to latex orthodontic elastics in a laboratory setting. The sample size used was six elastics and different comparable sizes were tested from two companies. Tests were done to

determine cyclic loading and unloading forces, dry loading at different lengths and load relaxation over 24 hours.

The cyclic testing was used to compare the loading and unloading curves of the elastics and the elastics were cycled from nominal to three times internal diameter 50 times at 1Hz. The mean data from the last 5 cycles was used to calculate various material properties including peak load, peak stress, linear stiffness, tangent modulus, and percent hysteresis. An average of six repeated tests were used to measure force levels at two and three times internal diameter. In all cases the initial force levels were below marketed levels at two times internal diameter and equal to or above at three times internal diameter. These findings were similar to the findings of Kanchana and Godfrey[2] and were different from the findings of Bales et. al.[20] which showed marketed force values at two times internal diameter. Fracture point was measured along with the dimensional measurements of the elastics. The GAC® non-latex elastics were larger in cross-section than their latex equivalents but Masel's® non-latex elastics did not differ or tended to be smaller in cross section when compared to their latex equivalents.

The load relaxation tests done by Russell et. al. used a new method that allowed them to leave the elastics stretched and take readings on the apparatus. Most studies have taken the elastics out to measure force levels and then replaced them into the testing apparatus. Strain gauges on cantilevers were used to measure the forces generated by the elastics during the load relaxation testing. Error was reported as 0.5 gm. The elastics were tested

by extending them until their marketed force was reached and observing forces generated by the elastics over a 24 hour period. The study reported:

> "there were non consistent similarities between the GAC latex and Masel latex elastics. The Masel non-latex elastics consistently maintained greater loads than the GAC non-latex elastics except at 1 hour, when the medium and heavy elastics produced the same force levels"

All the GAC® latex elastics maintained higher force levels than GAC® non-latex elastics except at 1 hour when there was no statistically significant difference. Masel® non-latex elastics maintained higher forces than their latex elastics.

This study was well done and was a good reference for those using the products presented. This study provided more insight into the mechanical properties of the different materials and products. However, it would have been interesting to compare the force decay properties of the elastics extended to the same distances. The methods used may have given a clearer picture of the true material properties than extending to a set distance but clinically elastics are extended to a set distance rather than a known force. Cyclic testing in a clinical simulation would also have provided more information about the differences between the materials and products.

1-4 Testing Methodology Review

The testing apparatus used for this research was designed with the goal of simulating a clinical environment as much as it is realistic to do so. Prior to the study by Russell et. al.[1] measurements of forces were done with hand held measuring gauges, spring gauges or Instron testing machinery. One disadvantage of those previous techniques was the

necessity for removal of the material from the testing apparatus and its placement into a measuring device.

Binocular beams, with strain gauges applied to them, were used to measure forces in the testing apparatus. A previous study used similar beams to measure forces produced by orthodontic closing springs that produced forces similar to those that were expected. [26] The system in that study was calibrated with dead weights and could measure forces up to 5N with an accuracy of 3.6% and moments of 40Nmm with an accuracy of 4.5%.[26] Since the inception of this project Russell et. al.[1] published a study that used a similar system to measure forces with strain gauge cantilevers. The measurement theory was the same for the Russell et. al. system as that used by Faulkner et. al. [1, 26] An applied force created an alteration in current flow through the strain gauges when the cantilever beam flexed, resulting in a change in output voltage. The change could be converted into a force measurement by calibrating the individual beams for specific changes in voltage for known loads.

The second unique component of the testing apparatus was its simulation of opening and closing. Previous studies have tested elastics that were repeatedly stretched and relaxed to simulate chewing [4, 9]. Other studies have used personal communications and vague references to justify the distances to extend stretched elastics to simulate chewing. The University of British Columbia has created a model that simulates human jaw function on a computer in three dimensions.[27] Information from their computer simulation was used to estimate change in length of the elastics with wide opening. Information on the change

in distance from the middle of tooth 13 to the middle of tooth 46 was requested from their model with wide opening. From this information the average change in distance was 24.7 mm with a 50mm interincisal distance, which might be considered an average maximal opening. This was less than the distance of 3 cm used by Liu et. al.[4] but more than that estimated by Bishara and Andreason.[16] A weakness of this information was that it considered a full dentition and the starting distance was slightly greater than 3 times marketed internal diameter for ¼"(6.35mm) elastics that are commonly used.

Most studies have used a distilled 37°C water bath to test elastomeric materials. Saliva may be more ideal but would have been unrealistic for the testing that was done. Dry testing was unnecessary since it has been shown that elastomerics lose force more rapidly when exposed to water. In vivo testing has also shown that for shorter testing periods water was equivalent to in vivo findings [21] however the evidence was not extremely strong in this regard.

1-5 Research Objectives

1. Develop a justifiable in vitro testing procedure for orthodontic elastics for both static and cyclic testing of force decay.
2. Determine if there are significant differences between non-latex orthodontic elastics and traditional latex orthodontic elastics with respect to force delivery for interarch mechanics.

3. Develop recommendations to equalize force delivery from non-latex orthodontic elastics with that of latex orthodontic elastics.
4. Determine whether or not there are significant differences between non-latex elastics from different suppliers

1-6 Research Questions and Hypotheses

1. What is the effect of static stretching on force decay of latex and non-latex orthodontic elastics?

Ho:

There is no significant difference in force decay with static stretching between latex and non-latex orthodontic elastics.

Ha:

There is a significant difference in force decay with static stretching between latex and non-latex orthodontic elastics.

2. What is the effect of cyclic stretching on force decay of latex and non-latex orthodontic elastics?

Ho:

There is no significant difference in force decay with cyclic stretching between latex and non-latex orthodontic elastics.

Ha:

There is a significant difference in force decay with cyclic stretching between latex and non-latex orthodontic elastics.

3. ***Is there a significant difference in force delivery between non-latex elastics from different suppliers?***

Ho:

There is no significant difference in force decay between non-latex orthodontic elastics from different suppliers.

Ha:

There is a significant difference in force decay between non-latex orthodontic elastics from different suppliers.

1-7 References

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Chapter 2 - Research Paper #1

A Comparison of Dynamic and Static Testing of Latex and Non-latex Orthodontic Elastics

2-1 Introduction

Previous studies have reported on forces generated by orthodontic elastics over time when tested in both static and dynamic (cyclic testing) environments. This study investigated the effects of cyclic and static testing on the forces generated over time for two different types of orthodontic elastics. This knowledge will allow orthodontists to assess the inherent forces generated by these different products at different times and should help to improve treatment delivery for interarch mechanics.

While there are multiple surveys of natural rubber latex (latex) orthodontic elastics and other synthetic elastomeric materials (i.e. elastic ligatures, elastomeric chain) there is limited research on synthetic (non-latex) orthodontic elastics. Russell et. al.[1] recently published an in vitro assessment of the mechanical properties of latex and non-latex elastics that provided some insight into these products' behavior. The latex and non-latex elastics were not similar in their behavior. Furthermore, force delivery over time varied with the manufacturer.

The majority of the orthodontic elastics on the market are latex elastics. Since the early 1990's synthetic products have been offered on the market for latex-sensitive patients and are sold as non-latex elastics. There is limited information on the risk that latex elastics may pose to patients. Some have estimated that 0.12-6 % of the general population and 6.2 % of dental professionals have hypersensitivity to latex protein. [2] There are some reported cases of adverse reactions to latex in the orthodontic population but these are

very limited to date.[3,4] While the risk is not yet clear it would still be inadvisable to prescribe latex elastics to a patient with a known latex allergy.

The most recent survey of latex elastics was written by Kanchana et. al.[5] A number of different types of elastics were tested and extension and force information was provided in the results. The elastics were tested statically and one of the recommendations was that future studies look at the effect of repeated stretching (cyclic testing). Liu et. al.[6] studied the effect of cycling on latex elastics and found that there was more force loss with cyclic testing but the effect was not statistically different beyond 200 cycles.

The purposes of this study were to determine the differences between the latex and non-latex orthodontic elastics from one company with respect to force production and force decay over time and to determine the differences between static and cyclic testing of these same elastics.

2-2 Materials and Method

2-2-1 Testing Apparatus

The testing apparatus was designed by the authors and custom made at the Department of Mechanical Engineering at the University of Alberta. (Figure 2-1) The design permitted testing of six elastics submerged in a 37°C distilled water bath. Temperature was maintained by a submersible heater (George Ulanet Co. Model 324 Heet-O-Matic) with

an internal thermostat (accuracy ± 0.6°C). The force-measuring component of the apparatus consisted of a series of six binocular beams with strain gauges (in full bridge configuration). These beams have been used in the past to measure forces similar to what we had expected. [7] Each beam was calibrated independently to determine its accuracy and sensitivity.

The elastics were attached to hooks and one end (left side of Figure 2-1) was able to move freely on a set of runners with bearings while the force measuring end (right side of Figure 2-1) was held securely. A stepper motor (Nema 23 5-wire high torque) was used to cycle the elastics when tested dynamically and the system was locked at a set length for static testing. An adjustable pin and slot mechanism attached to the motor's shaft allowed for adjustment of the cycling amplitude. The stepper motor was controlled by software supplied with the motor by Steppercontrol.com (Mill-Shaf Technologies, Inc. Yadkninville, NC USA) and run with a laptop computer and an A-200 stepper motor controller from Steppercontrol.com. Output from the binocular beams was sent to a Hewlett Packard E1401A data acquisition system and a custom written LabVIEW (National Instruments Inc.) software program on a desktop personal computer.

2-2-2 Pilot Study and Error Analysis

A pilot study was completed to look at sample variability and testing apparatus error. Six ¼" 4.5oz (6.35mm, 127.5gm) latex and non-latex elastics were tested in each group. The samples were from the same supplier (American Orthodontics Inc.® 1714 Cambridge

Avenue, P.O. Box 1048 Sheboygan, WI USA 53082-1048). Results from this study were used to determine sample sizes for further study and to look for error in the testing apparatus.

Sample size calculations were performed using Mintab for Windows and used a sample size calculation formula that required input of estimated standard deviation, desired power and desired minimum detectable difference. [8] A maximum standard deviation of 7% was observed in force decay values in the pilot study and was used in the calculations. 80% power was used since higher power yielded unreasonably high sample sizes and a minimum desired detectable difference chosen was 10%. The formula also assumed that four groups would be compared in the study. The result of these calculations was a required sample size of 12 elastics.

Individual binocular beams were calibrated by loading them with 0, 10, 20, 50, 100, 200 and 250gm loads and measuring output voltage. R squared values were 0.999 for all six of the beams used indicating a nearly perfect linear relationship between the load applied and voltage output.

Error of the testing apparatus was determined by loading each testing beam with a known load and determining the variation over an eight-hour period. (See Appendix 1) The error in the system was ±3% for a fixed 100gm load.

2-2-3 Study Design

A sample size of 12 elastics per group was used for this study. Samples were obtained close to the testing time from the manufacturer and were within their expiration dates. The elastics were stored as recommended in sealed bags in a cool and dark environment. Any distance measurements that were required were taken using electronic digital calipers with a marketed accuracy of 0.02mm (Lee Valley Tools Ltd., Item #88N6207, P.O. Box 6295, Station J Ottawa Ont. K2A-1T4).

Two materials were tested under two different testing methods yielding four test groups. The elastics were compared by testing six elastics at one time with a mixture of the two types of elastic tested at the same time. ¼" 4.5oz (6.35mm, 127.5gm) latex and non-latex elastics from American Orthodontics® were either cycled or statically tested. Both groups were initially stretched to 3 times the marketed internal diameter (19.05mm). The static groups were held at this length while the cycled groups were stretched an additional 24.7mm beyond this initial stretch with a cycle duration of 1 second and a frequency of 1 cycle/minute. The cycling distance was chosen using data provided by a computer model of the masticatory system that has been created by the University of British Columbia.[9] A request was made for the change in distance from the upper right canine to the lower right first molar with wide opening. This distance changed 24.7mm with a maximal opening of 50mm.

Forces generated by the elastics were recorded immediately after they were placed in the apparatus and at 0.5, 1, 1.5, 2, 4, 8, 16 and 24 hours. (See Appendix 2) Forces were always measured at three times marketed internal diameter. Another twelve elastics per type (twenty-four total) were tested to determine the initial forces generated when stretched to two times internal diameter (1/2" or 12.7mm) to allow for comparisons of initial force values at this stretched distance.

2-3 Results

A summary of initial forces generated by American Orthodontics'® ¼" 4.5oz (6.35mm, 127.5gm) latex and non-latex elastics when stretched to 2 and 3 times marketed internal diameter (12.7mm and 19.05mm) is presented in Table 2-1 along with descriptive statistics for both extension distances. Both types of elastics had similar standard deviations and had relatively large ranges of initial force. Paired t-tests were done using SPSS for Windows (SPSS Inc.) and found that both the latex ($P<0.01$) and non-latex ($P<0.0001$) elastics differed statistically from the marketed force level of 4.5oz (127.5gm).

Figure 2-2 displays what happened over the 24 hour testing period in the four groups. The changes that are seen represent the changes in percent of initial force. All groups showed force decay over time with greatest force loss in the first 30 minutes. Table 2-2

shows the mean percent initial force along with descriptive statistics for the different elastic materials and testing methods (See Appendix 2 for complete data set).
SPSS for Windows (SPSS Inc.) was used to compare the groups and a multiple comparison ANOVA was done to determine statistically significant differences between the materials and testing methods. (See appendix 3 for statistical output) The difference between materials was not statistically significant early in testing but became significant at 8 hours into testing $P<0.0001$. The difference between cycling and static testing was highly significant at 30 minutes ($P<0.0001$). Percentage of initial force remaining at the 24 hour force recordings were 74.6% for the latex cycled elastics compared to 82.7% for the statically tested latex elastics. The non-latex elastics had percent initial force remaining at 24 hours of 53.2% for the cycled group compared to 68.7% for the static group.

2-4 Discussion

The testing methods used in this study attempted to simulate interarch use of orthodontic elastics in a laboratory setting. While water bath testing is probably the most realistic medium for large-scale testing of orthodontic elastomers this medium may only be adequate for short term testing. [10] The dynamic testing scenario estimated distance changes with wide opening from a model based on averages [9] and the distances and frequency of stretching used may have been on the higher side of average clinical distances. However, others have used similar estimations in the past for interarch

mechanics and the values used were within the "clinical ranges" used by Liu et. al. [6] and Bishara and Andreason.[11]

The majority of studies have tested orthodontic èlastics in a static environment. Cyclic testing of orthodontic elastics, whether latex or non-latex, led to significantly more force loss in this study. The non-latex elastics were more affected than their latex counterparts were. This could have been due to more chain slippage at the molecular level due to repeated stretching or it could be due to extension beyond the elastic limit of the product or a combination of both. Cycling of the elastics also caused a larger decrease in force early in testing but the force decay rate was similar to that of the statically tested elastics after the first hour. These findings were similar to what was observed by Liu et. al. and earlier studies.[6, 12] Liu et. al. reported that after 200 cycles there was no significance to further cycling with respect to force decay. There was some recovery of forces generated by the cycled elastics in the study by Liu et. al. after repeated stretching, but this study was unable to assess this phenomenon due to the testing methods that spread the cycling throughout the test period.

While the distance the elastics were cycled was not arbitrary, the choice of 1 cycle per minute was relatively arbitrary and was chosen by the authors to reflect a balance between the higher frequency of opening seen during chewing and the lower frequency seen at other times. Cycles were spread out in an attempt to better simulate the conditions in the mouth of an orthodontic patient.

Based on results from this study and those of Liu et. al.[6], cyclic testing of orthodontic elastics used for interarch mechanics should be a component of material testing to get a clearer picture of actual forces being delivered over time. The difference in percentage of decrease from initial force, which could be attributed to cycling, was 15.6% in the non-latex elastics and 8.2% for the latex elastics over the 24 hour test period. The different effects seen for the two materials was further support for cyclic testing of new materials since some materials may be better than others at withstanding repeated stretching. With further testing, it may be possible to determine a relatively consistent percentage initial force loss that could be used as an estimate for cycling for various materials. This would allow for broader testing without the difficulties posed by a cyclic testing apparatus and the expense of apparatus design and fabrication.

The force measurement system used in this study was new but similar to that used by Russell et. al.[1] A significant advantage of the systems used in this study, and the study by Russell et. al., was the ability to test over time without removing the samples for hand measurement or Instron testing. One of the conclusions reached by Russell et. al. was that "the mechanical properties of non-latex elastics cannot be assumed to be-and indeed are not- the same as those of latex elastics".[1] Russell et. al. found that there were differences between the GAC® non-latex and Masel® non-latex products. The GAC® elastics retained approximately 60% of initial force after 24 hours while the Masel® elastics faired better retaining approximately 75% of their initial force. The Masel® non-latex elastics maintained forces similar to the latex elastics studied in their experiment. The results of this study are similar since they indicate a difference between the latex and

non-latex products we tested but the results were closer to the results seen for the GAC® elastics in the study by Russell et. al.. This study found that American Orthodontics'® latex elastics maintained higher force levels over time with 83% of initial force remaining at 24 hours vs. 69% of initial force remaining at 24 hours for the non-latex elastics when tested statically. The results showed a continuing force loss for the non-latex elastics that became statistically different from the latex elastics after 8 hours of testing.

This study only compared one company's latex elastic with its non-latex elastic. In addition, only one size and force level of elastic was studied. However, the results should allow for more educated use of American Orthodontics'® latex and non-latex elastics. Similar to the study by Russell et al [1] the results indicate a significant difference between the two materials. Different processes may be causing the forces to decline in the elastics and these differences are likely related to differences in the structure of the polymers involved. Since composition of non-latex elastics is proprietary, speculation is all that is possible. The non-latex elastics, as a synthetic elastomer, may rely more on molecular entanglement for structural integrity rather than covalent cross linking that is present in natural rubber latex products. [1] This structural difference may result in the poorer long-term performance of the non-latex elastics and could allow other environmental factors such as moisture and heat to have different and more negative effects.

What amount of force degradation is significant? There is no clear answer to this question and it may depend on the magnitude of the force and the precision desired by the clinician. There is no consensus in the literature but others have used a 10% difference as

a measure that could be clinically significant when looking at elastomeric chain.[13] 10% is probably a reasonable number and should be kept in mind when discussing the results above and relating them to the clinical setting.

The first clinical note is that there was variability within the same samples. Standard deviations were similar to those seen in recent studies.[1,5] Forces generated at 2 and 3 times marketed internal diameter were measured and the results were different from previous studies. Contrary to what Bales reported this study found that at two times marketed internal diameter the elastics generated forces well below the marketed force.[14] Other more recent studies have also observed that the majority of elastics tested produced higher than marketed forces at 3 times marketed internal diameter.[1,5] Why these results differ from previous studies is not entirely clear but it could indicate that there are differences between suppliers and/or batches that could exist. None of American Orthodontics'® products was tested in the studies referenced above so direct comparisons are limited.

Clinical use of elastics would ideally start with a measurement of the attachment points and selection of the elastic that would require stretching to 3 times internal diameter to extend over that distance. It would be advisable to assess a sample of the elastics you purchase to determine a range of forces you may see since a product may not perform precisely as specified by the manufacturer. A second clinical point is that with these latex elastics approximately 25% of force was lost in 24 hours with the majority of force loss occurring in the first hour. The non-latex elastics lost nearly 50% of their force over the 24 hour period. The non-latex elastics reached 75% of initial force in the first hour,

which was where the latex elastics were after 24 hours. The non-latex elastics had approximately 63% of their force remaining at 8 hours which is what may occur if a patient were to change elastics three times daily. Clinically, the decision will have to be made about whether to start with a higher force than deemed necessary or end up with a lower force than desired after a very short time in the mouth. Further study is needed using different brands of latex and non-latex elastics along with different sizes and force levels. This would help to determine whether the results of this study are comparable to what might be seen on a larger scale among different manufacturers.

2-5 Conclusions

1. American Orthodontics'® latex elastics (1/4" 4.5ox, 6.25mm 127.5g) retained significantly more force over time than their non-latex equivalents.
2. Cyclic testing of orthodontic elastics caused significantly more force loss than static testing but this effect was seen early in testing and did not change the rate of force decay after this.
3. Due to higher rates of force loss that continued throughout testing it is more important that non-latex elastics be changed at regular intervals not exceeding 6-8 hours.
4. Due to variability in force delivery it is advisable for practitioners to test a sample of their elastics prior to using them or purchasing large quantities to ensure that the force levels are in the expected range.

2-6 References

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A.

B.

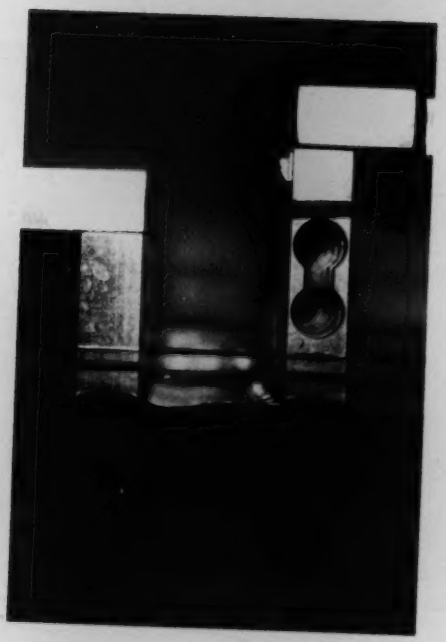

Figure 2-1 A. Elastic testing apparatus. B. View of elastics in the testing apparatus.

Table 2-1 Initial forces and descriptive statistics at two extensions.

American Orthodontics® ¼" (6.35mm)4.5oz (127.5g)	2 x Internal Diameter (1/2", 12.7mm) Force (gm)			3 x Internal Diameter (3/4",19.05 mm) Force (gm)		
	N	Mean (SD)	Range	N	Mean (SD)	Range
Latex	12	53.74 (*6.93*)	43.81-64.66	24	122.22 *(*9.21*)	106.91-141.43
Non-latex	12	55.41(*7.02*)	46.88-69.44	24	118.29 **(*6.64*)	104.51-130.00

Paired t-test comparisons used to compare actual forces generated with marketed forces.
*Significantly different from manufacturer's value at P<0.01
**Significantly different from manufacturer's value at P<0.0001

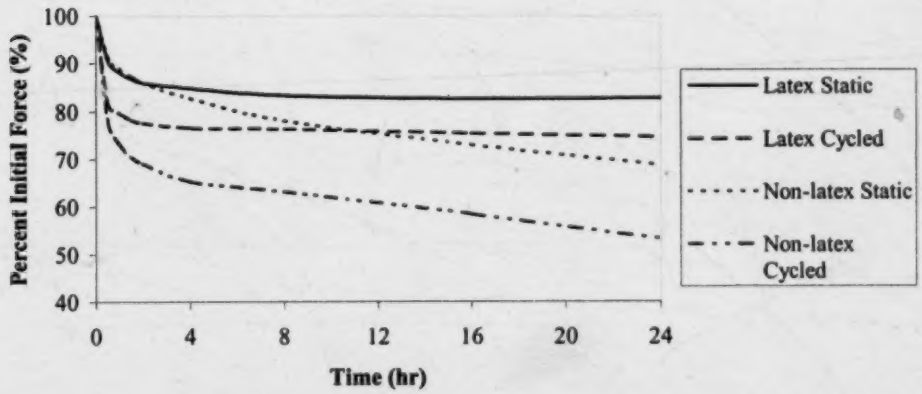

Figure 2-2 Mean percent initial force over time grouped for elastic material and testing method.

Table 2-2 Grouped data for percent of initial force over time and descriptive statistics.

Time (hr)	Material	Testing Method	% Initial Force			
			Min	Max	Mean	SD
.5	Latex	Cycled*	78.26	85.02	81.46	1.86
		Static*	88.73	91.74	90.42	0.75
	Non-latex	Cycled*	74.95	80.20	77.53	1.52
		Static*	89.41	93.18	91.28	1.24
1.0	Latex	Cycled*	77.60	84.37	79.65	1.70
		Static*	85.65	89.18	88.14	1.09
	Non-latex	Cycled*	60.65	78.38	73.12	6.04
		Static*	86.92	91.03	88.87	1.34
1.5	Latex	Cycled*	75.69	82.20	78.17	1.69
		Static*	84.29	88.24	86.77	1.26
	Non-latex	Cycled*	57.91	76.57	70.43	6.15
		Static*	85.22	88.99	87.17	1.12
2.0	Latex	Cycled*	74.49	82.28	77.58	1.85
		Static*	82.96	87.47	85.92	1.43
	Non-latex	Cycled*	57.13	74.91	69.04	5.81
		Static*	83.95	87.89	85.96	1.18
4.0	Latex	Cycled*	73.13	80.88	76.56	2.20
		Static*	82.86	86.54	84.72	1.26
	Non-latex	Cycled*	54.04	70.51	65.32	5.11
		Static*	80.17	84.88	82.70	1.32
8.0	Latex**	Cycled*	72.59	82.11	76.34	2.60
		Static*	81.03	84.95	83.29	1.17
	Non-latex**	Cycled*	50.15	67.56	63.08	5.01
		Static*	73.06	80.22	78.04	2.13
16.0	Latex**	Cycled*	70.90	80.60	75.37	2.72
		Static*	80.62	85.97	82.65	1.71
	Non-latex**	Cycled*	50.01	62.66	58.48	4.67
		Static*	65.37	81.10	73.02	4.57
24.0	Latex**	Cycled*	70.99	79.66	74.55	2.91
		Static*	80.37	87.39	82.74	1.90
	Non-latex**	Cycled*	44.98	57.96	53.16	4.31
		Static*	58.23	78.09	68.73	6.12

*Statistically significant difference between testing methods P<0.0001.
** Statistically significant difference between materials P<0.0001.

Chapter 3 - Research Paper #2

An In Vitro Comparison of Four Brands of Non-Latex Orthodontic Elastics

3-1 Introduction

During the past several years there has been an increasing awareness of the health risks posed by some natural rubber latex (latex) products. Traditionally, latex elastics have been used for interarch mechanics and other intraoral elastic uses. A number of companies have started to market synthetic (non-latex) orthodontic elastics. Demand for these products may increase as awareness of latex sensitivity increases in both the orthodontic population and among orthodontic practitioners and staff.

Russell et. al. [1] compared two brands, and three sizes, of non-latex orthodontic elastics as well as the equivalent latex elastics from the same manufacturer. There were significant differences between the latex and non-latex elastics and between the different brands. The two non-latex elastics had different dimensions and different initial force generation properties for the equivalent marketed size and force level, as well as different force decay properties over time.

Most studies of orthodontic elastics examined force delivery over time in a static environment. Few studies have looked at the effects of dynamic testing (cyclic testing) of orthodontic elastics. The one relatively recent study that did investigate these effects found that the effect of cycling was significant and caused a further decrease in the force compared with static testing.[2]

A recent survey of latex orthodontic elastics by Kanchana et. al.[3] provided good reference tables for force extension relationships and force decay over time for static testing. The authors recommended further study and cyclic testing was one of their recommendations along with other physiological variables such as pH and thermal cycling.

The purpose of this study was to compare the force decay properties of four brands of non-latex orthodontic elastics with similar marketed forces and sizes in a clinically relevant simulation of interarch elastic wear.

3-2 Methods and Materials

A testing apparatus was designed and fabricated to allow for cyclic testing of orthodontic elastics (Figure 3-1). The apparatus consisted of a tank of distilled water that was temperature controlled by a submersible water heater (George Ulanet Co. Model 324 Heet-O-Matic) with a reported accuracy of ±0.6°C. On one end of the tank (right side Figure 3-1) the force-measuring component of the apparatus was anchored. This consisted of a series of 6 binocular cantilever beams with strain gauges (in full bridge configuration) to which one end of the six elastics being tested were attached. Similar beams have been used to measure forces generated by orthodontic retraction springs in a laboratory setting.[4] On the other end of the tank (left side of Figure 3-1) was a sliding mechanism that could be cycled back and forth at a set distance using a stepper motor (Nema 23 5-wire high torque, Mill-Shaf Technologies, Inc. Yadkninville, NC USA). The

motor was controlled by a laptop computer and an A-200 controller (Mill-Shaf Technologies, Inc. Yadkninville, NC USA).

Output readings from the strain gauges were sent to a Hewlett Packard E1401A data acquisition system controlled by a custom written program in LabVIEW (National Instruments Inc.). Output from the binocular beam load cells was in the form of a voltage reading. The voltage outputs were converted into forces in Excel (Microsoft Corp) using each individual beam's calibration curve.

A pilot study was performed to investigate the variability in elastic samples and to estimate error in the measurement system. Six non-latex and latex elastics were tested cyclically and statically and force measurements were gathered over 24 hours.

Sample size calculations were completed using Mintab for Windows and a sample size calculation formula that required input of the following variables [5]:

- Estimated standard deviation (7%)
- Desired power (80%)
- Minimum detectable difference desired (10%)
- Number of comparisons (4)

Calculations were done prior to completing the study and the values in brackets were used in the formula. The estimated standard deviation used was the maximum standard deviation seen in the pilot study results for percentage of initial force. Higher power yielded unreasonably high sample sizes so 80% was used. Output from these calculations led to the selection of a sample size of 12 for further study.

An error analysis was performed to determine the error in the testing apparatus. 100gm loads were placed on each of the beams and output readings were taken over an eight hour period. Based on observed variability, the error in the system was observed to be ±3%. (See Appendix 1)

This study used 12 elastics in each group. Four brands were tested and all the samples were obtained close to the testing date and stored as per manufacturer's instructions. Table 3-1 is a summary of the brands tested and their marketed sizes and forces. All of the elastics were within the recommended expiry date on the product packaging. Six elastics were tested at one time and were randomly assigned to each measuring beam so that no one elastic type was measured more often on one of the beams. The elastics were placed between two hooks set at a distance of 19.05mm (or 3 times marketed internal diameter for ¼" (6.35mm) elastics). After installation, the elastics were never relaxed below this distance and were cycled throughout the testing period an additional 24.7mm once per minute with a cycle duration of 1 second. The cycling distance was determined using a model developed by the University of British Columbia. [6] The change in distance between the upper right canine and lower right first molar with wide opening was requested. This distance change was 24.7mm with an interincisal distance of 50mm. Any measurements that were taken to set initial stretching distances were obtained using electronic digital calipers (Lee Valley Tools Ltd., Item #88N6207) that had a stated accuracy of 0.02mm. A force level reading was taken as soon as the elastics were set into the system within 10 seconds and this reading was taken to be time 0. Cycling was started after this first reading. The computer collected data at intervals for a 24 hour

period while the elastics were stretched to 3 times lumen size (i.e. not during the stretching cycles). Another 12 elastics per group were tested for initial force only at two times marketed internal diameter or 12.7mm extension. (See Appendix 4 for complete data set)

Dimensions of 12 elastics were measured from each of the samples that were tested above. One brand of latex elastic (American Orthodontics®) of similar size and weight was also measured for comparison purposes. Thickness, width and internal diameter size were measured using the digital calipers described above under magnification. Four points on the elastics were measured for thickness and width and two points for internal diameter. Cross-sectional area was estimated by multiplying the average thickness by the average width for each elastic. The two measurements of internal diameter were averaged to estimate an effective internal diameter. Five elastics were measured at two different times and the measurements were compared to determine if the error in the measurement technique was statistically significant. Data analysis was done using SPSS for Windows software (SPSS Inc.).

3-3 Results

The initial forces generated by the elastics at 2 and 3 times marketed internal diameter extension are shown in Table 3-2. Paired sample t-tests indicated that all of the elastics had force levels that were statistically different from the marketed force as indicated in Table 3-2. GAC® elastics had initial force levels higher than marketed while the others

were below the marketed force levels. There was a large amount of variation in initial forces generated at 3 times marketed internal diameter within the samples with larger variation seen for the GAC® and Ortho Organizers® elastics compared to those for the American Orthodontics® and Masel® elastics.

Due to the wide range of initial forces, decreases over time were compared by percentages of initial force. Percentages of initial force for all brands are included in Table 3-3 along with descriptive statistics at selected time points.

Figure 3-2 illustrates the force decay patterns of the four brands of elastics. They all behaved in a very similar pattern. Multiple comparison ANOVA was used to assess differences between the brands at different time points.(See Appendix 5 for statistical output) There was no statistically significant difference between American Orthodontics®, Ortho Organizers® and GAC® elastics regardless of time. There were some statistically significant differences between the Masel® elastics and the rest of the group (See Table 3-3). Differences were seen in the ability of the Masel® elastics to survive the 24 hours of cyclic testing and statistical comparisons between Masel® elastics and the other groups after eight hours should be viewed with caution. Figure 3-3 shows the brands and the number of elastics that failed during testing and the approximate time of the failure.

Independent sample t-tests were completed to assess error in the dimensional measurement technique. Comparisons were made between dimensional measurements

for each of the five elastics that were measured at two separate times. (See Appendix 6) There were no statistically significant differences between the repeated measurement dimensions between the two times.(See Appendix 7) Figures 3-4 and 3-5 show boxplots of the cross-sectional and internal diameter measurements for the different elastics tested in this study and the equivalent latex elastic from American Orthodontics® (See Appendix 8 for dimension data). ANOVA was used to compare the different elastics for statistically significant differences in cross-sectional area and internal diameter. American Orthodontics® and Ortho Organizers® were not significantly different from one another with respect to internal diameter and cross-sectional area. GAC® and Masel® elastics differed significantly from all of the other groups $P<0.0001$. The latex elastics did not differ from the Ortho Organizers'® or American Orthodontics'® non-latex elastics with respect to internal diameter but were statistically different from the Masel® and GAC® elastics. The cross-sectional dimension of the latex elastics was also statistically different from the American Orthodontics'® and Ortho Organizers'® non-latex elastics. Figure 3-6 illustrates the variability between brands in thickness. A strong statistical correlation was observed between the average cross-sectional area of the different non-latex elastics and the forces they generated (Correlation Coefficient 0.841) (See Figure 3-7).

The change in appearance seen in Figure 3-8 was representative of what was observed throughout testing. There was permanent deformation, swelling and a change from transparent to opaque in all of the non-latex brands. Visually, there was almost no effect on the latex elastic.

3-4 Discussion

The elastics tested were not all homogeneous with respect to marketed force but should, from a clinical perspective, behave in a similar way and represented each company's middle weight elastic that was marketed as being ¼" (6.35mm) and 4 or 4.5oz (113gm or 128gm) force. Among the four brands, two were not significantly different from each other with respect to initial force generation while the other two differed significantly from all other brands. Previous surveys have found similar variability between supposedly equivalent products.[1, 3, 7] Initial force values observed in this study were different from the findings of Russell et. al. [1] Russell et. al. found that Masel's® medium non-latex elastics produced on average 155.1gm of force when stretched to 3 times the marketed internal diameter. This force was much higher than the 113gm force the elastics were marketed as having. In this study the Masel® elastics had significantly lower forces than marketed (113gm) at an extension of three times marketed internal diameter with an average of 92.3gm force generated. However, the GAC® elastics tested compared more closely to the results seen by Russell et. al..[1] Russell et. al. observed an average force of 140.7gm at three times marketed internal diameter compared to 159.0gm seen in this study. Changes in size or material composition may have occurred since the study by Russell et. al.. The observation that three of the four brands tested in this study generated forces below the marketed force level at 3 times internal diameter was also different from previous studies. Most studies have found that 3 times internal diameter extension generally produces higher than marketed forces.[1, 3, 8]

Force decay was compared using percentage of initial force rather than actual force generated. The different brands of elastic behaved in an almost identical pattern up until the time when some started to fail during testing. The differences between brands were seen in breakage times. Only one out of twelve Masel® elastics survived the entire 24 hours of testing however none of these elastics failed prior to 12 hours into testing. Until the elastics failed, they appeared to maintain a similar percentage of initial force as the other brands with a statistical trend of lower force levels. The number of failures may not be relevant since most patients will be changing the elastics at every meal however elastic performance through the important night time period could lead to clinically significant differences. There was a statistical difference in percentage of initial force between the GAC® and Ortho Organizers® elastics and the Masel® elastics at four hours and later in the testing at 16 hours and 24 hours. No consensus on force delivery and clinical relevance exists. However, it has been suggested that a 10% difference between products may be clinically significant when comparing chain elastomers. [9] In this study the difference in force decay between the Masel® elastics and the others was clinically insignificant when breakages were not included however comparisons involving the Masel® elastics after 8 hours was unreliable due to the decrease in the sample size due to breakage.

The dimensions of the elastics were also measured using a sample of each brand tested and an equivalent latex elastic. There was a strong correlation between the cross-sectional area of the elastics and the forces generated at the initial extension. Previous studies using latex elastics have suggested that thicker elastics maintain higher forces

over time while smaller elastics are more consistent in their force delivery but may be more susceptible to creep and show more force loss over time. [7] The results from this study tended to support this idea since there were differences between the smaller Masel® elastics and the GAC® elastics in the percentage of initial force generated over time. No statistically significant correlation was seen in our study between variability in cross-sectional area and variability in initial force generation at extension. The method, in this study, for measuring dimensions differed from the study by Russell et. al. [1] that used a Mitutoyo non-rotating thickness gauge. This study used electronic digital calipers. Direct comparisons of dimensional measurements between the studies may have some measurement differences associated with them since these results showed consistently thicker measurements than those observed by Russell et. al. [1] These results found that the GAC® elastics had an average cross-sectional area that was larger than the others while the Masel® elastics had an average cross sectional area smaller than the others. This similar pattern was seen by Russell et. al. between the non-latex Masel® and GAC® elastics. The American Orthodontics® and Ortho Organizers® elastics were not statistically different. The force decay and dimensional analyses suggest that the elastics studied have the same underlying material presented in different forms.

The effect of water absorption on elastics has been shown to be significant and this effect is increased force decay due to interference at the secondary bond sites. [10] Recent study of synthetic elastomeric chain found that heat had the most significant effect on those materials when compared to acidity and oxygen content.[11] Further investigation is needed to determine the underlying causes of the force loss in the materials that were

tested in this study. The appearance of the non-latex materials at the end of testing appeared to be more comparable to what is seen with synthetic elastomeric chain in the clinical setting compared to what may be seen with latex orthodontic elastics. Some investigators have suggested pre-stretching of synthetic elastomeric chain to create more efficient force delivery by reducing the initial decrease seen to occur.[10, 11] Further study is needed with non-latex elastics to assess force delivery after pre-stretching to determine if this would be beneficial.

Clinical use of these new products requires caution. Among the non-latex brands tested significant variation was seen in the initial forces generated at the same extension distance and the forces generated were all significantly different than marketed. In addition, nearly 50% the initial force was lost in all of these elastics over the 24 hour testing period. More importantly, nearly 25% of force loss occurred in the first 30 minutes. At 4 and 8 hours the force levels were near 65% and 60% respectively. The clinician is forced to choose between initial forces that may be much higher than desired or a force near the desired amount that will decay after a short time to levels below those that may be required for the desired effects to be seen.

3-5 Conclusions

1. American Orthodontics'® and Ortho Organizers'® ¼" 4.5oz (6.35mm, 127.5gm) elastics generated equivalent initial forces at an extension of 3 times marketed

internal diameter that were statistically below their marketed force levels of 127.5gm. (116.1gm and 114.9gm respectively)

2. GAC® ¼ "4oz (6.35mm, 113gm) non-latex elastics generated significantly higher forces at an extension of 3 times marketed internal diameter than marketed. 159.0gm actual vs. 113.0gm marketed.
3. Masel® ¼" 4oz (6.35mm, 113gm) non-latex elastics generated significantly less force than marketed at an extension of three times marketed internal diameter. 92.3gm actual vs. 113.0gm marketed.
4. The four brands had similar force decay curves until 12 hours at which time some of the elastics failed more than the others did.
5. The average cross-sectional area of the elastics was strongly correlated with the initial forces generated.

3-6 References

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Table 3-1 Non-latex brands tested in this study and their marketed properties.

Product Supplier	Marketed Properties	
	Internal Diameter	Force Level
American Orthodontics ®[a]	¼" (6.4mm*)	Medium 4.5oz (127.5gm)
Ortho Organizers ®[b]	¼" (6.35mm*)	Medium 4.5oz (127.5gm)
GAC International ®[c]	¼" (6mm*)	H6 Heavy 4oz (113gm)
Masel ®[d]	¼" (6.4mm*)	Heavy 4oz (113gm)

a. American Orthodontics Inc. ®, 1714 Cambridge Avenue, P.O. Box 1048 Sheboygan, WI USA 53082-1048

b. Ortho Organizers Inc. ® 1619 S. Rancho Santa Fe Rd. San Marcos, CA 92069.

c. GAC International Inc. ® 185 Oval Drive, Central Islip, NY 11722 USA

d. Masel Inc. ® Bristol, PA 19007-6892 USA

*1/4" is equivalent to 6.35mm.

Table 3-2 Initial force levels at different extensions.

Brand of Elastic	2 x Marketed Internal Diameter (1/2", 12.7mm) Force (gm)			3x Marketed Internal Diameter (3/4",19.05 mm) Force (gm)		
	N	Mean(SD)	Range	N	Mean (*SD*)	Range
American Orthodontics®	12	47.2*(8.4)*	31.8 – 59.9	12	116.1**(6.8)*	105.6 - 132.8
Ortho Organizers®	12	50.6*(6.5)*	40.5 – 61.2	12	114.9***(13.1)*	97.1 - 134.2
GAC®	12	73.6*(8.5)*	61.9 – 83.7	12	159.0**(13.4)*	138.5 - 176.4
Masel®	12	49.5*(5.4)*	37.5 – 59.1	12	92.3**(7.7)*	80.5 - 107.4

*Significantly different from manufacturer's marketed value P<0.0001

**Significantly different from manufacturer's marketed value P<0.01

Table 3-3 Percentage of initial force and descriptive statistics for different brands.

Time(hr)	Brand		% Initial Force			
		N	Minimum	Maximum	Mean	SD
0.5	American Ortho	12	76.1	79.8	77.8	1.6
	Ortho Organizers	12	74.7	82.0	77.9	2.2
	GAC	12	76.4	81.2	79.0	1.7
	Masel	12	74.6	81.6	78.5	1.6
1.0	American Ortho	12	71.2	76.8	74.5	1.7
	Ortho Organizers	12	72.1	79.1	75.3	2.0
	GAC	12	73.3	79.2	76.2	1.6
	Masel	12	73.4	79.5	75.3	1.7
1.5	American Ortho	12	68.7	76.1	72.7	2.0
	Ortho Organizers	12	69.5	78.3	73.5	2.3
	GAC	12	71.6	77.6	74.7	1.6
	Masel	12	71.0	78.2	73.4	1.8
2.0	American Ortho	12	68.0	74.9	71.5	1.8
	Ortho Organizers	12	68.9	77.0	72.3	2.3
	GAC	12	70.4	76.7	73.3	1.6
	Masel	12	67.7	76.9	71.7	2.1
4.0	American Ortho	12	63.8	70.7	67.0	1.8
	Ortho Organizers	12	64.8	78.1	68.9*	3.6
	GAC	12	65.0	72.0	68.9*	1.9
	Masel	12	58.7	72.0	65.7*	3.3
8.0	American Ortho	12	44.1	69.2	59.4	6.5
	Ortho Organizers	12	50.3	73.7	62.1	6.2
	GAC	12	53.2	67.8	63.4	3.7
	Masel	12	53.8	63.0	59.2	2.9
16.0	American Ortho	12	44.5	60.2	53.7**	4.8
	Ortho Organizers	12	46.5	60.2	54.5**	4.6
	GAC	12	48.2	62.7	57.6**	4.4
	Masel	8	33.1	56.1	46.1**	8.3
24.0	American Ortho	11	39.3	56.1	48.0**	6.0
	Ortho Organizers	9	43.2	57.1	49.2**	4.9
	GAC	11	45.8	58.9	53.5**	4.7
	Masel	1	41.1	41.1	41.1**	.

*Masel differs with Ortho Organizers and GAC $P<0.05$.

**Masel differs from all others $P<0.0001$.

A.

B.

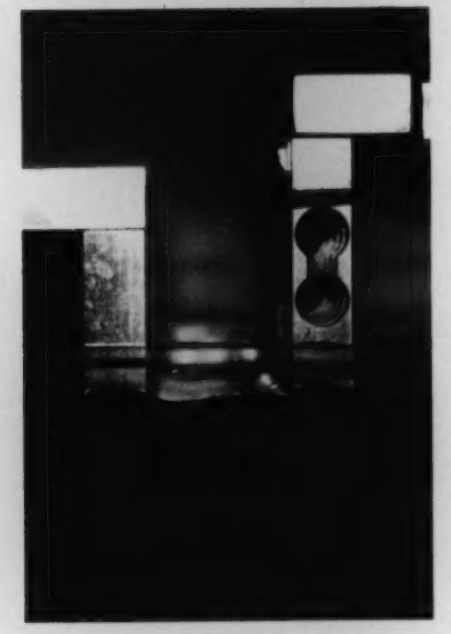

Figure 3-1 A. Elastic testing apparatus. B. View of elastics in the testing apparatus.

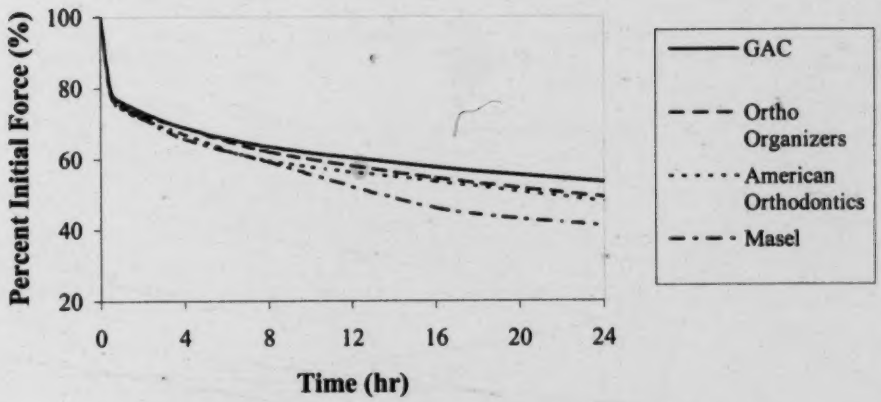

Figure 3-2 Force decay over time for elastics that survived testing.

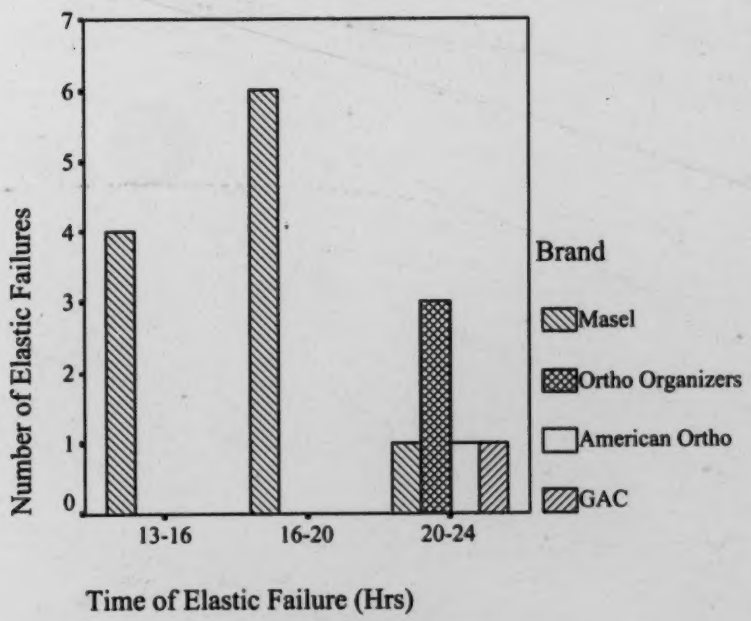

Figure 3-3 Elastic failures by brand and time.

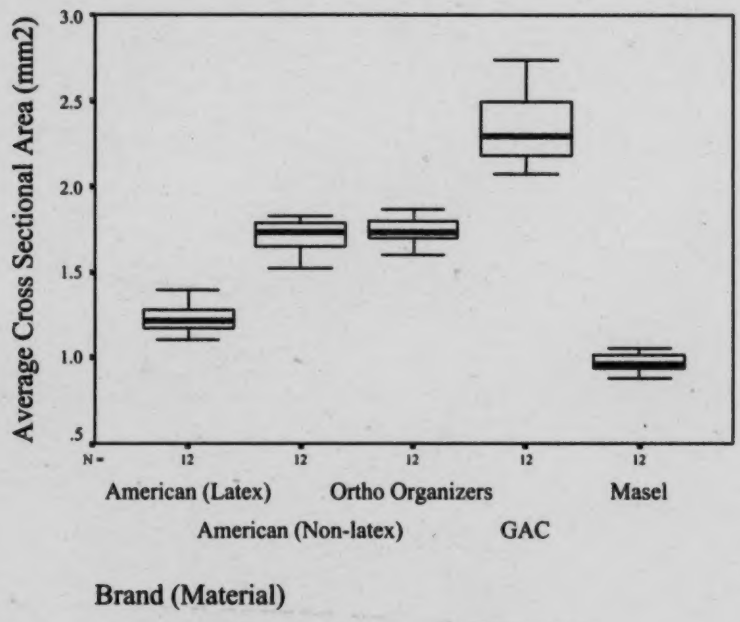

Figure 3-4 Box plots of average cross-sectional area.

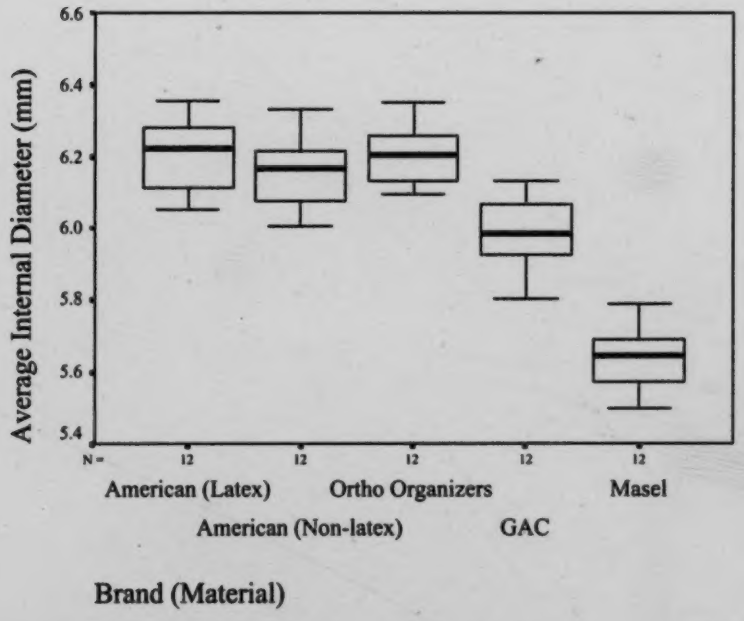

Figure 3-5 Box plots of average internal diameters.

Figure 3-6 Samples tested. Left to right. American Orthodontics (Latex), American Orthodontics (Non-Latex), Ortho Organizers, GAC, Masel.

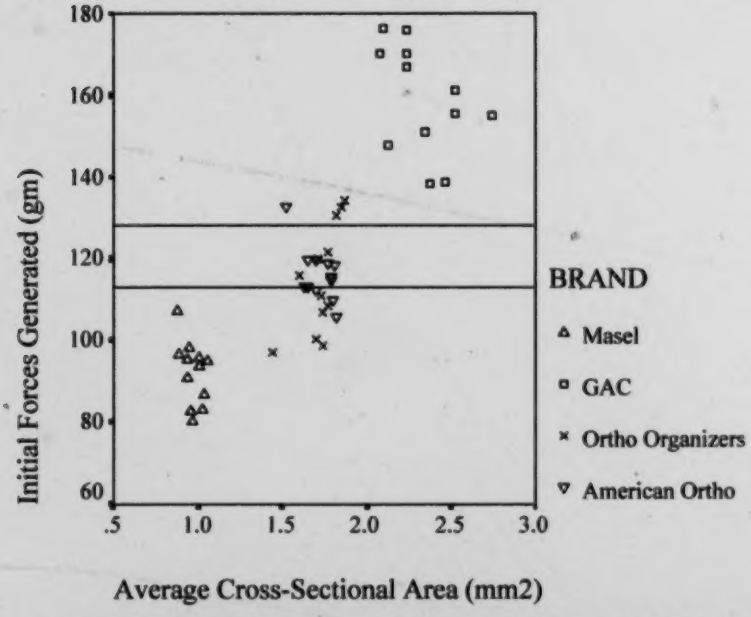

Figure 3-7 Cross-sectional area and initial force generation. Statistically significant correlation coefficient 0.841 and P<0.01. Horizontal lines represent marketed force levels of 113gm and 128gm.

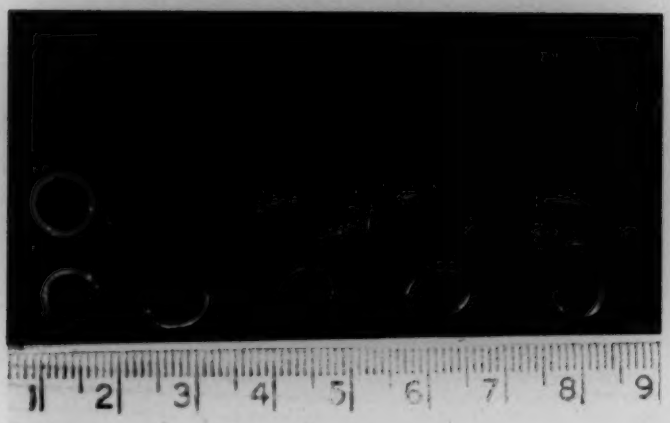

Figure 3-8 Samples after 24 hours testing and equivalent untested samples. Left to right. American Orthodontics (Latex), American Orthodontics (Non-latex), Ortho Organizers, GAC, Masel.

Chapter 4 - General Discussion

4-1 Introduction

This research had several objectives. The first objective was to develop a testing environment that would allow for assessment of the force delivery properties of elastics in the laboratory under simulated interarch elastic wear. The second objective was to compare and contrast latex and non-latex materials and some different brands of non-latex elastics. The overall goal of the studies was to improve orthodontic treatment delivery by arriving at some recommendations with respect to elastic use for interarch mechanics when using non-latex orthodontic elastics.

4-2 Testing Method

The testing apparatus was relatively unique. The force measuring component of the apparatus was based on previously used methods and allowed the samples to be tested without removal from the environment.[1] This force measuring methodology was similar to that used by Russell et. al.[2] and should be considered for future studies of force decay of orthodontic materials. There was some error in the system but the 3% error observed should be insignificant and many previous studies have used hand gauges and measured to the closest 10gm or 10%.[3, 4, 5]

No other English language study, found by the authors, has used a similar method for cycling orthodontic elastics. The use of the stepper motor was advantageous since it allowed for accurate control of the cycling for timing, speed and position. Previous

studies have used motorized cycling devices for single elastics.[3, 6] One study looked at creep in the elastics and cycled the elastics 1cm total.[6] The most recent study cycled the elastics prior to measuring forces with hand gauges and monitoring force decay over an extended period.[3] The system used in this study appeared to produce a reasonable simulation of mouth opening and closing compared to those mentioned above. In addition, this system was able to measure multiple elastics and did not have to remove them from the system for force measurements. The system was designed with adjustments and could be used to test for different cycle distances in the future. The distance the elastics were cycled was based on estimates from a computer model under the assumption of wide opening.[7] This distance may not be accurate for all cases, but it was probably a good estimate of what could be seen clinically and was between the ranges for elastic stretch used by others in the past.[3, 8]

There are no standardized methods for elastic testing and there is mixed evidence about the reliability of water bath testing as a simulation for in vitro testing.[9, 10] However, this is probably the method of choice for large scale short term testing of elastomerics. The testing environment in this study was also temperature controlled since both temperature and water have been shown to contribute to increased force decay in elastomerics.[11, 12] The system used in this study was adaptable and could be used to test in a dry state or with other variables in the system.

4-3 Cyclic vs. Static Testing

Cyclic testing increased force loss over and above static testing for both latex and non-latex elastics in Study 1. A maximum effect was seen that occurred early. This study was unable to assess the exact time that the plateau was reached but like the study by Liu et. al. [3] the results suggested that the effect of cycling was limited. While the effect of cycling on both materials was statistically significant, it had more effect on the non-latex elastics. The difference at 24 hours, in terms of % initial force, was approximately 16% for the non-latex elastics and 8% for the latex elastics. Ten percent has been considered a clinically significant difference but there is no clear answer and it is probably situation dependent.[5]

The significant differences in the results observed for the two materials illustrated the importance of cyclic testing. However, with more study it may be possible to estimate the amount of cyclic effect and limit this type of testing to smaller samples of a specific material to decrease cost and time.

4-4 Latex vs. Non-latex Materials

There were differences, which appeared to be clinically relevant, between the latex and non-latex materials from one company. The results were not unexpected as Russell et. al.[2] also found differences between the materials. While the two studies' results were similar this study found more differences between the latex and non-latex products with

respect to force decay patterns. The differences between the results from the two studies could have been due to testing methodology or product source and differences.

Study 1 results generated no direct comparisons with the Russell et. al.[2] study but Study 2 tested two elastics that Russell et. al.[2] tested. The results were quite different for both of the elastics but especially when comparing the results for the Masel® elastics. There may have been a product change since the previous study was completed that could account for the differences. In addition, the two studies could only be directly compared for initial force values since this study tested the elastics cyclically. Cyclic testing only was used in Study 2. This was considered, by the authors, a better simulation of what may be seen clinically. From the results of the Pilot and Study 1, dynamic testing was shown to be significantly different that static testing.

Study 1 illustrated the material differences between American Orthodontics'® latex and non-latex elastics. The force decay patterns were significantly different and the latex elastics seemed to maintain a very slow rate of force decay after initially rapid force loss while the non-latex elastics had a more rapid and continued force decay throughout the testing period. The higher rate of force loss would likely be clinically relevant. If patients were to wear their elastics longer than the prescribed amount of 6-8 hours the elastics would continue to lose force unlike traditional latex elastics. Previous studies have suggested that latex elastics could be used for longer intervals since after the initial force loss they are relatively stable with respect to force delivery.[8, 13] It would seem reasonable for patients to wear latex elastics over longer periods up to 24 hours if desired.

However, for all of the non-latex elastics tested short term wear is all that could be recommended. Patients should change these elastics at a maximum of 8 hours to have a minimum of approximately 65% of the initial force. If this is not enough force for the required effect, these products should probably not be used or should be changed more often. To account for early force decay in the latex elastics a clinician could start with an extra 25% of the desired long-term force but it may be unreasonable to start with 50% more force which could be required for long term use of the non-latex elastics that were tested.

4-5 Non-latex Brand Comparison

Study 2 compared four brands of elastics. While they were all marketed with similar sizes and force levels they were quite different. Size differences were seen upon opening different brand packages. A clinician that had a new order of elastics from only one company would not have observed these differences. This illustrated one of the problems that clinicians may face in practice. The results suggest a cautious approach to new materials and a need for a small sampling of a new product.

The two brands (American Orthodontics® and Ortho Organizers®) that had similar dimensions had comparable initial force values and could have been from the same source presented in different packaging. The relationship between cross-sectional area and force production was well correlated. There were some indications of improved

force retention of the elastics with larger cross section but this was small and not considered clinically relevant.

The four brands tested were shown to have similar force decay patterns and the results did not indicate clinically significant differences in this regard. The Masel® elastics failed more often but not before 12 hours into testing. Clinically, this could be considered advantageous since by 12 hours into the test the forces generated would be nearly 40% lower than initial forces and would likely be below the desired amount. Elastic breakage may act as a reminder to the patient to change the elastics.

4-6 Clinical Implications

A cautious approach to purchasing a new material, or a material from another supplier should be taken. Products sold as "equivalents" may not be similar in their force generation and dimensional properties. While differences between brands were large in some cases each of the products could be considered useful for different situations.

For the office using American Orthodontics'® products, they should first decide what approximate force they wish to apply. These studies only examined the middleweight elastics from this company and further study is necessary, using other sizes, but the results should be useful as a guide until further detailed studies are done. If a practitioner chooses non-latex elastics they should expect these to undergo greater force decay than latex equivalents. The amount may be clinically relevant early into use with an average

difference of nearly 8% as early as 1.5 hours into elastic use. However, differences that are more significant were somewhat delayed and started to increase four hours into testing. When using the non-latex products, patients should be advised to change the elastics every 6-8 hours minimum, while a patient could conceivably wear latex elastics up to 24 hours since the forces generated were relatively stable after the initial hour for American Orthodontics'® latex elastics.

For the office that has decided to limit its inventory to non-latex materials for worker and patient safety concerns they must find a way to account for the poorer long-term behavior of the non-latex materials. The products tested had similar force decay patterns but some were completely different with respect to force generation with extension. For this reason clinicians should consider asking for a sample of elastics prior to purchase. They could then assess whether the force delivery characteristics of those elastics are "in the ball park" prior to purchasing a large order. The practitioner should expect to see differences between suppliers but small sample testing could allow them to adjust accordingly. There may be risks to both the practitioner and patients if this testing is not done. The most significant risk would be to the patient and could result from excessive forces or forces that are inadequate. Pain, tissue damage or extended treatment time could result. The risks to the practitioner may be a lack of treatment progress, delayed treatment times or patient unhappiness. A common sense approach is critical to new product selection. The practitioner must take responsibility for the product and not accept products that are not performing as indicated by the suppliers.

4-7 Future Research

The first area that requires more research is the effect of cyclic testing vs. static testing. If elastomeric materials are tested to determine the point at which the effect of cycling is significant further testing of the materials could be simplified. This could allow for less expensive and broader testing of orthodontic elastics in the future. Information from some of the other suppliers should be gathered to compare the differences between their latex and non-latex elastics. If a similar pattern to the one seen for American Orthodontics'® elastics is seen further cyclic testing may not be necessary. Future large-scale size and force studies could utilize static testing methods that save time and equipment costs. However, use of a system that allows force measurements to be made without removing the materials from the testing apparatus should be considered since it eliminates the possibility of drying out with removal that could cause some recovery of force.

Due to the limited samples tested further testing is needed on different sizes of elastics similar to those done by Kanchana et al.[13] This is especially important for the non-latex brands. If a larger survey were performed assessments of whether each company offers an acceptable range of forces from different elastic sizes and forces could be made. Companies may have the desired product but it may be labeled incorrectly.

It would also be interesting to assess latex and non-latex elastics under different testing conditions such as pH and thermal cycling. Studies have compared the effects of

different environments on synthetic orthodontic elastomeric chain but it would be interesting to see the different effects on latex and non-latex elastics. By compiling more information on different possible environmental effects, further large scale testing of elastics could once again be simplified. However, as these studies have shown, the effects of one factor may be different for different products and new materials should be rigorously tested under all conditions if possible.

Another issue that needs to be addressed is how to apply an acceptable force to the teeth using these new products. According to these results nearly 25% of force is lost in the first 30 minutes and more decay occurs over time. Clinically this may be acceptable, if it is known and accounted for, but would more likely result in excessive initial forces or insufficient forces over the period the elastics are worn. Studies have looked at the effects of pre-stretching for elastomeric chains and have recommended that this be done to even out force delivery.[11, 12] Future studies of these non-latex elastics need to assess whether this would be effective and how much stretching would be required. One issue with pre-stretching elastics is that clinicians would have to rely on the patient to pre-stretch the elastics. Ideally, if it were shown that the effect of stretching was stable it may be possible to apply a pre-stretch to the material during the manufacturing process prior to cutting the tubing. Further information is needed to assess these possibilities.

4-8 General Conclusions

1. Cyclic testing caused significantly more force loss early in testing compared to static testing for one company's latex and non-latex elastics but did not change the force decay pattern after this early effect.
2. American Orthodontics'® non-latex elastics lost more force over time than their latex equivalents and were more adversely affected by cyclic testing.
3. The force decay properties of non-latex elastics from American Orthodontics®, Ortho Organizers®, GAC® and Masel® did not appear to be clinically different in the first 8 hours of testing however the ability of the elastics to survive testing after 12 hours was very different.
4. There may be significant differences, with respect to initial force generation, between equivalent or near equivalent products from different suppliers.

4-9 References

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Appendices

Appendix 1 – Testing Apparatus Error Analysis Data

Beam Number and Force (gm)						
Time	1	2	3	4	5	6
0.0	99.02026	99.36632	97.83321	99.96862	97.45946	97.59273
0.5	98.74615	99.84417	98.6622	100.2733	98.10816	98.54534
1.0	98.84125	99.58162	98.51606	100.473	97.91252	98.38614
1.5	98.94194	99.75228	98.55638	100.0045	98.34241	98.13194
2.0	98.68741	99.93606	98.55638	100.9901	98.7028	98.58128
2.5	99.41185	100.1172	98.8789	100.7495	98.73111	98.89454
3.0	99.59645	100.4795	98.78819	101.2871	98.57666	98.41695
3.5	99.12655	100.4323	98.74284	100.857	98.65389	98.37074
4.0	98.90838	100.2275	98.5463	100.6573	98.34498	97.90856
4.5	99.13774	100.0096	98.80331	100.9184	98.39647	98.56331
5.0	99.21605	100.1198	98.7504	100.8109	98.41449	98.7071
5.5	99.451	100.2485	98.83859	101.0977	98.19826	98.45547
6.0	99.21046	99.94394	98.75795	100.7802	98.65389	98.47858
6.5	99.52932	100.2748	98.80331	100.9338	98.88556	98.70967
7.0	99.5461	100.133	98.66724	100.5959	98.23687	98.44777
7.5	99.17689	100.0096	98.67984	100.8468	98.32439	98.25776
8.0	99.49016	99.91768	98.62693	100.8109	98.59468	98.58128

Appendix 2 - Data Sets for Study #1

Force generated at 2 times internal diameter (gm)		
Sample	American Non-latex	American Latex
1	46.9	46.9
2	58.6	45.5
3	49.5	51.5
4	46.9	59.1
5	50.0	53.9
6	51.6	56.1
7	69.4	46.0
8	63.8	57.7
9	58.1	43.8
10	53.5	64.7
11	60.8	58.0
12	55.8	61.7

American orthodontics Latex (L) and Non-latex(NL) elastics
Both static and cyclic testing of 1/4" 4.5 Oz elastics
Forces generated at 3 times internal diameter.

Elastic #	% initial force	Force(gm)	L/NL(1/2)	Cycled/Static(1/2)	time (hr)
1	100.00	104.51	2	2	0
2	100.00	117.57	2	2	0
3	100.00	112.89	2	2	0
4	100.00	116.89	2	2	0
5	100.00	123.17	2	2	0
6	100.00	115.86	2	2	0
7	100.00	119.67	2	2	0
8	100.00	121.86	2	2	0
9	100.00	108.40	2	2	0
10	100.00	125.16	2	2	0
11	100.00	117.73	2	2	0
12	100.00	123.74	2	2	0
13	100.00	133.27	1	2	0
14	100.00	140.52	1	2	0
15	100.00	134.73	1	2	0
16	100.00	106.91	1	2	0
17	100.00	113.95	1	2	0
18	100.00	115.32	1	2	0
19	100.00	137.34	1	2	0
20	100.00	124.84	1	2	0
21	100.00	124.33	1	2	0
22	100.00	116.55	1	2	0
23	100.00	117.28	1	2	0
24	100.00	115.33	1	2	0
25	100.00	119.30	2	1	0
26	100.00	111.00	2	1	0
27	100.00	129.53	2	1	0
28	100.00	120.31	2	1	0
29	100.00	117.34	2	1	0
30	100.00	112.70	2	1	0
31	100.00	113.19	2	1	0
32	100.00	112.93	2	1	0
33	100.00	121.60	2	1	0
34	100.00	113.78	2	1	0
35	100.00	130.00	2	1	0
36	100.00	129.87	2	1	0
37	100.00	112.21	1	1	0
38	100.00	120.08	1	1	0
39	100.00	129.30	1	1	0
40	100.00	118.12	1	1	0
41	100.00	119.55	1	1	0
42	100.00	121.72	1	1	0

43	100.00	116.66	1	1	0
44	100.00	117.06	1	1	0
45	100.00	141.43	1	1	0
46	100.00	117.86	1	1	0
47	100.00	120.82	1	1	0
48	100.00	118.09	1	1	0
1	91.40	95.52	2	2	0.5
2	91.60	107.69	2	2	0.5
3	93.07	105.07	2	2	0.5
4	91.05	106.43	2	2	0.5
5	90.17	111.06	2	2	0.5
6	89.42	103.60	2	2	0.5
7	92.08	110.20	2	2	0.5
8	92.08	112.22	2	2	0.5
9	93.18	101.01	2	2	0.5
10	91.19	114.12	2	2	0.5
11	90.72	106.81	2	2	0.5
12	89.41	110.64	2	2	0.5
13	90.26	120.29	1	2	0.5
14	88.73	124.68	1	2	0.5
15	89.92	121.15	1	2	0.5
16	90.83	97.11	1	2	0.5
17	90.78	103.45	1	2	0.5
18	90.96	104.89	1	2	0.5
19	91.74	126.00	1	2	0.5
20	89.99	112.35	1	2	0.5
21	90.21	112.16	1	2	0.5
22	90.63	105.64	1	2	0.5
23	90.96	106.68	1	2	0.5
24	90.02	103.82	1	2	0.5
25	78.75	93.94	2	1	0.5
26	76.15	84.53	2	1	0.5
27	77.10	99.86	2	1	0.5
28	79.01	95.06	2	1	0.5
29	80.20	94.10	2	1	0.5
30	78.96	88.99	2	1	0.5
31	77.93	88.21	2	1	0.5
32	77.94	88.02	2	1	0.5
33	74.95	91.14	2	1	0.5
34	76.53	87.08	2	1	0.5
35	76.50	99.45	2	1	0.5
36	76.29	99.07	2	1	0.5
37	82.27	92.32	1	1	0.5
38	81.48	97.84	1	1	0.5
39	80.40	103.96	1	1	0.5
40	85.02	100.43	1	1	0.5
41	81.29	97.19	1	1	0.5

42	80.33	97.77	1	1	0.5
43	78.26	91.30	1	1	0.5
44	79.37	92.91	1	1	0.5
45	84.09	118.94	1	1	0.5
46	81.25	95.76	1	1	0.5
47	82.37	99.52	1	1	0.5
48	81.40	96.13	1	1	0.5
1	89.02	93.03	2	2	1
2	89.28	104.96	2	2	1
3	91.03	102.76	2	2	1
4	89.29	104.37	2	2	1
5	87.83	108.17	2	2	1
6	87.27	101.11	2	2	1
7	89.66	107.30	2	2	1
8	89.69	109.30	2	2	1
9	90.58	98.19	2	2	1
10	88.73	111.06	2	2	1
11	87.16	102.61	2	2	1
12	86.92	107.55	2	2	1
13	88.93	118.52	1	2	1
14	85.65	120.35	1	2	1
15	88.18	118.81	1	2	1
16	89.10	95.26	1	2	1
17	88.99	101.41	1	2	1
18	89.18	102.84	1	2	1
19	89.18	122.48	1	2	1
20	87.89	109.72	1	2	1
21	88.30	109.78	1	2	1
22	86.92	101.31	1	2	1
23	88.09	103.31	1	2	1
24	87.24	100.61	1	2	1
25	76.90	91.74	2	1	1
26	73.22	81.28	2	1	1
27	75.33	97.58	2	1	1
28	76.77	92.36	2	1	1
29	78.38	91.97	2	1	1
30	76.70	86.44	2	1	1
31	77.12	87.29	2	1	1
32	76.95	86.89	2	1	1
33	60.65	73.75	2	1	1
34	61.26	69.71	2	1	1
35	72.22	93.88	2	1	1
36	72.00	93.51	2	1	1
37	80.16	89.95	1	1	1
38	79.55	95.52	1	1	1
39	79.16	102.35	1	1	1
40	84.37	99.65	1	1	1

41	80.54	96.28	1	1	1
42	78.98	96.14	1	1	1
43	77.60	90.53	1	1	1
44	78.31	91.67	1	1	1
45	79.14	111.92	1	1	1
46	78.87	92.96	1	1	1
47	80.20	96.89	1	1	1
48	78.91	93.19	1	1	1
1	88.02	91.99	2	2	1.5
2	87.59	102.98	2	2	1.5
3	88.99	100.46	2	2	1.5
4	87.25	101.98	2	2	1.5
5	86.09	106.04	2	2	1.5
6	85.22	98.73	2	2	1.5
7	87.37	104.56	2	2	1.5
8	87.63	106.78	2	2	1.5
9	88.25	95.66	2	2	1.5
10	87.19	109.13	2	2	1.5
11	87.11	102.56	2	2	1.5
12	85.36	105.63	2	2	1.5
13	87.83	117.05	1	2	1.5
14	84.29	118.44	1	2	1.5
15	86.92	117.11	1	2	1.5
16	87.71	93.78	1	2	1.5
17	88.10	100.39	1	2	1.5
18	87.76	101.21	1	2	1.5
19	88.24	121.19	1	2	1.5
20	85.60	106.86	1	2	1.5
21	86.76	107.86	1	2	1.5
22	85.88	100.09	1	2	1.5
23	86.86	101.87	1	2	1.5
24	85.25	98.32	1	2	1.5
25	74.52	88.91	2	1	1.5
26	71.51	79.38	2	1	1.5
27	71.20	92.22	2	1	1.5
28	74.95	90.17	2	1	1.5
29	76.57	89.85	2	1	1.5
30	73.57	82.91	2	1	1.5
31	73.14	82.78	2	1	1.5
32	74.03	83.60	2	1	1.5
33	57.91	70.42	2	1	1.5
34	58.13	66.14	2	1	1.5
35	69.90	90.87	2	1	1.5
36	69.71	90.54	2	1	1.5
37	78.83	88.46	1	1	1.5
38	78.40	94.14	1	1	1.5
39	78.64	101.69	1	1	1.5

40	82.20	97.10	1	1	1.5
41	79.48	95.01	1	1	1.5
42	77.90	94.82	1	1	1.5
43	75.69	88.30	1	1	1.5
44	77.52	90.75	1	1	1.5
45	77.34	109.39	1	1	1.5
46	76.10	89.69	1	1	1.5
47	78.66	95.04	1	1	1.5
48	77.24	91.22	1	1	1.5
1	86.17	90.06	2	2	2
2	86.59	101.80	2	2	2
3	87.89	99.22	2	2	2
4	86.11	100.65	2	2	2
5	84.70	104.32	2	2	2
6	83.95	97.27	2	2	2
7	86.47	103.48	2	2	2
8	86.59	105.52	2	2	2
9	87.35	94.70	2	2	2
10	85.77	107.35	2	2	2
11	85.58	100.76	2	2	2
12	84.29	104.30	2	2	2
13	86.89	115.80	1	2	2
14	82.96	116.57	1	2	2
15	86.58	116.65	1	2	2
16	86.97	92.98	1	2	2
17	87.36	99.55	1	2	2
18	87.28	100.65	1	2	2
19	87.47	120.14	1	2	2
20	84.53	105.53	1	2	2
21	86.08	107.02	1	2	2
22	84.76	98.79	1	2	2
23	85.37	100.12	1	2	2
24	84.75	97.74	1	2	2
25	72.95	87.03	2	1	2
26	69.95	77.65	2	1	2
27	71.23	92.26	2	1	2
28	73.84	88.83	2	1	2
29	74.91	87.90	2	1	2
30	69.94	78.82	2	1	2
31	72.26	81.79	2	1	2
32	71.91	81.20	2	1	2
33	57.13	69.48	2	1	2
34	57.64	65.58	2	1	2
35	67.94	88.32	2	1	2
36	68.72	89.24	2	1	2
37	77.37	86.81	1	1	2
38	77.55	93.11	1	1	2

39	77.31	99.96	1	1	2
40	82.28	97.18	1	1	2
41	79.33	94.84	1	1	2
42	76.62	93.27	1	1	2
43	74.49	86.90	1	1	2
44	76.82	89.93	1	1	2
45	77.08	109.01	1	1	2
46	76.71	90.40	1	1	2
47	77.98	94.21	1	1	2
48	77.49	91.51	1	1	2
1	82.55	86.28	2	2	4
2	83.40	98.04	2	2	4
3	84.88	95.82	2	2	4
4	82.36	96.27	2	2	4
5	81.19	100.00	2	2	4
6	80.17	92.89	2	2	4
7	82.38	98.59	2	2	4
8	83.58	101.85	2	2	4
9	84.28	91.36	2	2	4
10	83.02	103.91	2	2	4
11	83.16	97.90	2	2	4
12	81.48	100.83	2	2	4
13	86.20	114.88	1	2	4
14	83.62	117.50	1	2	4
15	85.79	115.60	1	2	4
16	85.00	90.88	1	2	4
17	85.76	97.72	1	2	4
18	85.12	98.16	1	2	4
19	86.54	118.86	1	2	4
20	83.54	104.29	1	2	4
21	84.99	105.67	1	2	4
22	82.86	96.57	1	2	4
23	84.33	98.90	1	2	4
24	82.92	95.64	1	2	4
25	69.16	82.51	2	1	4
26	67.05	74.43	2	1	4
27	67.19	87.03	2	1	4
28	68.72	82.68	2	1	4
29	70.51	82.74	2	1	4
30	66.09	74.48	2	1	4
31	68.07	77.05	2	1	4
32	67.56	76.30	2	1	4
33	54.04	65.72	2	1	4
34	56.55	64.34	2	1	4
35	66.53	86.49	2	1	4
36	62.36	80.98	2	1	4
37	74.78	83.92	1	1	4

38	75.76	90.97	1	1	4
39	75.95	98.21	1	1	4
40	80.88	95.53	1	1	4
41	78.04	93.29	1	1	4
42	76.39	92.99	1	1	4
43	73.13	85.32	1	1	4
44	76.17	89.17	1	1	4
45	77.98	110.29	1	1	4
46	74.97	88.35	1	1	4
47	79.63	96.21	1	1	4
48	75.02	88.59	1	1	4
1	77.14	80.62	2	2	8
2	78.52	92.31	2	2	8
3	78.50	88.62	2	2	8
4	76.16	89.02	2	2	8
5	75.94	93.54	2	2	8
6	73.06	84.65	2	2	8
7	79.06	94.61	2	2	8
8	79.71	97.14	2	2	8
9	80.22	86.96	2	2	8
10	79.81	99.88	2	2	8
11	80.16	94.37	2	2	8
12	78.21	96.78	2	2	8
13	84.88	113.12	1	2	8
14	83.95	117.96	1	2	8
15	84.26	113.53	1	2	8
16	82.31	88.00	1	2	8
17	83.94	95.65	1	2	8
18	83.24	95.98	1	2	8
19	84.95	116.66	1	2	8
20	82.77	103.33	1	2	8
21	82.87	103.03	1	2	8
22	82.10	95.69	1	2	8
23	83.17	97.54	1	2	8
24	81.03	93.46	1	2	8
25	67.02	79.96	2	1	8
26	65.53	72.75	2	1	8
27	63.57	82.35	2	1	8
28	64.97	78.17	2	1	8
29	67.34	79.01	2	1	8
30	61.55	69.36	2	1	8
31	67.56	76.47	2	1	8
32	65.83	74.34	2	1	8
33	50.15	60.99	2	1	8
34	58.36	66.40	2	1	8
35	65.06	84.58	2	1	8
36	60.05	77.98	2	1	8

37	74.46	83.56	1	1	8
38	76.55	91.91	1	1	8
39	75.43	97.53	1	1	8
40	79.10	93.43	1	1	8
41	77.04	92.10	1	1	8
42	75.47	91.86	1	1	8
43	73.28	85.49	1	1	8
44	76.36	89.39	1	1	8
45	78.28	110.71	1	1	8
46	72.59	85.55	1	1	8
47	82.11	99.20	1	1	8
48	75.40	89.04	1	1	8
1	73.11	76.41	2	2	16
2	73.01	85.84	2	2	16
3	72.53	81.88	2	2	16
4	68.41	79.96	2	2	16
5	65.37	80.52	2	2	16
6	65.93	76.39	2	2	16
7	75.43	90.27	2	2	16
8	75.24	91.69	2	2	16
9	77.46	83.97	2	2	16
10	74.72	93.52	2	2	16
11	81.10	95.49	2	2	16
12	73.95	91.50	2	2	16
13	84.38	112.46	1	2	16
14	85.97	120.80	1	2	16
15	84.69	114.10	1	2	16
16	82.13	87.80	1	2	16
17	82.34	93.83	1	2	16
18	81.03	93.44	1	2	16
19	84.09	115.49	1	2	16
20	82.14	102.55	1	2	16
21	82.02	101.97	1	2	16
22	81.02	94.43	1	2	16
23	81.35	95.41	1	2	16
24	80.62	92.99	1	2	16
25	62.57	74.65	2	1	16
26	60.77	67.46	2	1	16
27	59.34	76.86	2	1	16
28	62.66	75.39	2	1	16
29	62.47	73.30	2	1	16
30	60.73	68.45	2	1	16
31	61.48	69.59	2	1	16
32	61.08	68.97	2	1	16
33	50.10	60.92	2	1	16
34	50.01	56.91	2	1	16
35	55.84	72.59	2	1	16

36	54.71	71.05	2	1	16
37	75.80	85.05	1	1	16
38	75.87	91.10	1	1	16
39	80.60	104.22	1	1	16
40	78.07	92.22	1	1	16
41	78.21	93.50	1	1	16
42	74.11	90.21	1	1	16
43	70.90	82.71	1	1	16
44	75.59	88.49	1	1	16
45	73.96	104.60	1	1	16
46	74.25	87.51	1	1	16
47	75.36	91.05	1	1	16
48	71.75	84.73	1	1	16
1	68.22	71.30	2	2	24
2	68.86	80.95	2	2	24
3	68.06	76.83	2	2	24
4	61.13	71.45	2	2	24
5	58.23	71.72	2	2	24
6	59.77	69.26	2	2	24
7	71.60	85.69	2	2	24
8	72.11	87.88	2	2	24
9	74.39	80.64	2	2	24
10	72.67	90.95	2	2	24
11	78.09	91.93	2	2	24
12	71.61	88.60	2	2	24
13	84.09	112.07	1	2	24
14	87.39	122.80	1	2	24
15	84.10	113.31	1	2	24
16	83.24	89.00	1	2	24
17	83.11	94.71	1	2	24
18	81.97	94.52	1	2	24
19	83.03	114.04	1	2	24
20	81.56	101.81	1	2	24
21	81.15	100.89	1	2	24
22	80.37	93.67	1	2	24
23	81.10	95.11	1	2	24
24	81.75	94.29	1	2	24
25	56.96	67.95	2	1	24
26	53.86	59.79	2	1	24
27	53.89	69.81	2	1	24
28	57.68	69.40	2	1	24
29	57.96	68.01	2	1	24
30	53.80	60.63	2	1	24
31	56.38	63.82	2	1	24
32	54.05	61.04	2	1	24
33	45.46	55.28	2	1	24
34	44.98	51.18	2	1	24

35	52.24	67.92	2	1	24
36	50.60	65.72	2	1	24
37	72.48	81.33	1	1	24
38	72.91	87.54	1	1	24
39	79.66	103.00	1	1	24
40	77.58	91.63	1	1	24
41	78.87	94.29	1	1	24
42	74.35	90.50	1	1	24
43	71.37	83.26	1	1	24
44	73.31	85.82	1	1	24
45	73.93	104.55	1	1	24
46	72.68	85.66	1	1	24
47	76.54	92.47	1	1	24
48	70.99	83.83	1	1	24

Appendix 3 - Multiple Comparison ANOVA Study #1

1=Latex 1=Cycled
2=Non-latex 2=Static

Parameter Estimates

Dependent Variable	Parameter	B	Std. Error	t	Sig.	95% Confidence Interval		Partial Eta Squared	Noncent. Parameter	Observed Power[a]
						Lower Bound	Upper Bound			
INFRTP5	Intercept	91.282	.405	225.264	.000	90.485	92.099	.999	225.264	1.000
	[LNL=1]	-.861	.573	-1.503	.140	-2.016	.294	.049	1.503	.312
	[LNL=2]	0[b]	.	.	.	.	.	.	.	.
	[CYSTATIC=1]	-13.755	.573	-24.003	.000	-14.910	-12.600	.929	24.003	1.000
	[CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=1] * [CYSTATIC=1]	4.796	.810	5.918	.000	3.163	6.430	.443	5.918	1.000
	[LNL=1] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=1]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
INFRT1	Intercept	88.870	.940	94.573	.000	86.976	90.764	.995	94.573	1.000
	[LNL=1]	-.731	1.329	-.550	.585	-3.410	1.947	.007	.550	.084
	[LNL=2]	0[b]	.	.	.	.	.	.	.	.
	[CYSTATIC=1]	-15.746	1.329	-11.849	.000	-18.425	-13.068	.761	11.849	1.000
	[CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=1] * [CYSTATIC=1]	7.256	1.879	3.861	.000	3.468	11.043	.253	3.861	.966
	[LNL=1] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=1]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
INFRT1P5	Intercept	87.172	.952	91.572	.000	85.253	89.090	.995	91.572	1.000
	[LNL=1]	-.406	1.348	-.301	.765	-3.119	2.308	.002	.301	.060
	[LNL=2]	0[b]	.	.	.	.	.	.	.	.
	[CYSTATIC=1]	-16.743	1.348	-12.437	.000	-19.456	-14.030	.779	12.437	1.000
	[CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=1] * [CYSTATIC=1]	8.145	1.904	4.278	.000	4.308	11.982	.294	4.278	.987
	[LNL=1] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=1]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
INFRT2	Intercept	85.956	.919	93.496	.000	84.103	87.808	.995	93.496	1.000
	[LNL=1]	-3.82E-02	1.300	-.029	.977	-2.659	2.582	.000	.029	.050
	[LNL=2]	0[b]	.	.	.	.	.	.	.	.
	[CYSTATIC=1]	-16.920	1.300	-13.014	.000	-19.540	-14.300	.794	13.014	1.000
	[CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=1] * [CYSTATIC=1]	8.587	1.839	4.670	.000	4.881	12.292	.331	4.670	.995
	[LNL=1] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=1]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
INFRT4	Intercept	82.704	.845	97.843	.000	81.001	84.408	.995	97.843	1.000
	[LNL=1]	2.020	1.195	1.689	.098	-.390	4.429	.061	1.689	.379
	[LNL=2]	0[b]	.	.	.	.	.	.	.	.
	[CYSTATIC=1]	-17.384	1.195	-14.543	.000	-19.793	-14.975	.828	14.543	1.000
	[CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=1] * [CYSTATIC=1]	9.219	1.691	5.453	.000	5.812	12.626	.403	5.453	1.000
	[LNL=1] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=1]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
INFRT8	Intercept	78.040	.887	87.948	.000	76.252	79.829	.994	87.948	1.000
	[LNL=1]	5.248	1.255	4.182	.000	2.719	7.777	.264	4.182	.983
	[LNL=2]	0[b]	.	.	.	.	.	.	.	.
	[CYSTATIC=1]	-14.958	1.255	-11.919	.000	-17.487	-12.429	.764	11.919	1.000
	[CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=1] * [CYSTATIC=1]	8.008	1.775	4.512	.000	4.432	11.585	.318	4.512	.993
	[LNL=1] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=1]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
INFRT16	Intercept	73.022	1.051	69.470	.000	70.903	75.140	.991	69.470	1.000
	[LNL=1]	9.626	1.487	6.475	.000	6.630	12.622	.488	6.475	1.000
	[LNL=2]	0[b]	.	.	.	.	.	.	.	.
	[CYSTATIC=1]	-14.541	1.487	-9.782	.000	-17.537	-11.545	.685	9.782	1.000
	[CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=1] * [CYSTATIC=1]	7.267	2.102	3.457	.001	3.030	11.503	.214	3.457	.922
	[LNL=1] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=1]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
INFRT24	Intercept	68.728	1.191	57.706	.000	66.329	71.128	.987	57.706	1.000
	[LNL=1]	14.011	1.684	8.319	.000	10.617	17.406	.611	8.319	1.000
	[LNL=2]	0[b]	.	.	.	.	.	.	.	.
	[CYSTATIC=1]	-15.572	1.684	-9.245	.000	-18.967	-12.178	.660	9.245	1.000
	[CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=1] * [CYSTATIC=1]	7.388	2.382	3.102	.003	2.587	12.189	.179	3.102	.858
	[LNL=1] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=1]	0[b]	.	.	.	.	.	.	.	.
	[LNL=2] * [CYSTATIC=2]	0[b]	.	.	.	.	.	.	.	.

a. Computed using alpha = .05

b. This parameter is set to zero because it is redundant.

Appendix 4 – Study #2 Force Data

Brands :
1= American®
2= Ortho organizers®
3= GAC®
4=Masel®

Forces (gm) generated at 2 times marketed internal diameter				
Sample	Brand			
	1	2	3	4
1	31.8	56.5	66.4	53.1
2	41.2	49.3	66.4	49.1
3	49.4	53.5	68.0	53.5
4	41.2	52.3	78.3	51.8
5	36.5	61.2	65.5	50.4
6	44.1	49.7	61.9	59.1
7	51.0	48.6	82.0	43.2
8	59.9	40.5	81.7	49.7
9	51.2	53.9	83.7	46.4
10	56.1	42.8	83.5	37.5
11	55.8	41.4	80.5	51.3
12	47.9	57.2	65.8	48.5

Forces generated at 3 times marketed internal diameter					
Sample #	Force(gm)	Percent	Brand	Time(hr)	Failure time(hr)
1	115.45	100.00	1	0	
2	112.89	100.00	1	0	
3	113.03	100.00	1	0	
4	109.81	100.00	1	0	
5	105.63	100.00	1	0	
6	114.59	100.00	1	0	
7	132.83	100.00	1	0	
8	118.44	100.00	1	0	
9	118.66	100.00	1	0	
10	112.10	100.00	1	0	
11	119.62	100.00	1	0	
12	119.75	100.00	1	0	
13	134.15	100.00	2	0	
14	130.57	100.00	2	0	
15	120.00	100.00	2	0	
16	111.16	100.00	2	0	
17	106.94	100.00	2	0	

18	132.78	100.00	2	0	
19	121.47	100.00	2	0	
20	97.11	100.00	2	0	
21	115.94	100.00	2	0	
22	100.48	100.00	2	0	
23	108.75	100.00	2	0	
24	98.85	100.00	2	0	
25	155.09	100.00	3	0	
26	138.54	100.00	3	0	
27	155.37	100.00	3	0	
28	161.41	100.00	3	0	
29	138.87	100.00	3	0	
30	150.99	100.00	3	0	
31	176.39	100.00	3	0	
32	170.36	100.00	3	0	
33	176.00	100.00	3	0	
34	147.75	100.00	3	0	
35	167.00	100.00	3	0	
36	170.29	100.00	3	0	
37	86.80	100.00	4	0	
38	95.60	100.00	4	0	
39	90.89	100.00	4	0	
40	95.75	100.00	4	0	
41	96.90	100.00	4	0	
42	93.69	100.00	4	0	
43	98.50	100.00	4	0	
44	80.54	100.00	4	0	
45	83.33	100.00	4	0	
46	82.78	100.00	4	0	
47	94.92	100.00	4	0	
48	107.36	100.00	4	0	
1	89.41	77.44	1	0.5	
2	86.56	76.67	1	0.5	
3	90.15	79.76	1	0.5	
4	85.07	77.47	1	0.5	
5	83.10	78.66	1	0.5	
6	89.68	78.27	1	0.5	
7	103.11	77.62	1	0.5	
8	91.41	77.18	1	0.5	
9	90.31	76.11	1	0.5	
10	88.15	78.64	1	0.5	
11	94.07	78.64	1	0.5	
12	92.27	77.05	1	0.5	
13	104.39	77.82	2	0.5	
14	97.49	74.67	2	0.5	
15	98.05	81.71	2	0.5	
16	91.18	82.02	2	0.5	

17	83.51	78.09	2	0.5	
18	101.49	76.43	2	0.5	
19	92.31	76.00	2	0.5	
20	74.53	76.75	2	0.5	
21	88.88	76.66	2	0.5	
22	78.07	77.70	2	0.5	
23	85.44	78.56	2	0.5	
24	77.43	78.33	2	0.5	
25	118.65	76.51	3	0.5	
26	111.78	80.68	3	0.5	
27	120.31	77.43	3	0.5	
28	130.49	80.85	3	0.5	
29	106.13	76.43	3	0.5	
30	117.62	77.90	3	0.5	
31	139.85	79.28	3	0.5	
32	133.06	78.10	3	0.5	
33	142.00	80.68	3	0.5	
34	118.23	80.02	3	0.5	
35	131.10	78.50	3	0.5	
36	138.22	81.17	3	0.5	
37	68.79	79.25	4	0.5	
38	73.71	77.10	4	0.5	
39	71.49	78.65	4	0.5	
40	78.13	81.59	4	0.5	
41	75.58	78.00	4	0.5	
42	73.66	78.62	4	0.5	
43	77.50	78.68	4	0.5	
44	60.09	74.61	4	0.5	
45	66.23	79.47	4	0.5	
46	65.72	79.39	4	0.5	
47	74.35	78.34	4	0.5	
48	84.64	78.84	4	0.5	
1	85.96	74.46	1	1	
2	84.25	74.63	1	1	
3	86.78	76.78	1	1	
4	79.19	72.11	1	1	
5	75.22	71.21	1	1	
6	87.62	76.46	1	1	
7	98.60	74.23	1	1	
8	88.81	74.99	1	1	
9	87.60	73.82	1	1	
10	85.41	76.20	1	1	
11	90.16	75.37	1	1	
12	88.89	74.23	1	1	
13	100.90	75.22	2	1	
14	96.06	73.57	2	1	
15	94.90	79.08	2	1	

16	87.10	78.36	2	1	
17	78.74	73.63	2	1	
18	98.89	74.48	2	1	
19	87.56	72.08	2	1	
20	72.40	74.56	2	1	
21	86.70	74.78	2	1	
22	75.99	75.63	2	1	
23	82.36	75.74	2	1	
24	75.10	75.98	2	1	
25	114.94	74.12	3	1	
26	108.14	78.05	3	1	
27	117.26	75.47	3	1	
28	123.52	76.53	3	1	
29	101.82	73.32	3	1	
30	114.18	75.62	3	1	
31	134.32	76.15	3	1	
32	128.34	75.33	3	1	
33	139.44	79.23	3	1	
34	114.39	77.42	3	1	
35	127.39	76.28	3	1	
36	131.76	77.38	3	1	
37	65.94	75.97	4	1	
38	70.40	73.64	4	1	
39	67.65	74.43	4	1	
40	76.12	79.50	4	1	
41	71.70	73.99	4	1	
42	69.78	74.48	4	1	
43	73.42	74.54	4	1	
44	59.07	73.35	4	1	
45	63.81	76.57	4	1	
46	63.67	76.92	4	1	
47	70.90	74.70	4	1	
48	81.12	75.56	4	1	
1	84.89	73.53	1	1.5	
2	81.96	72.60	1	1.5	
3	84.92	75.13	1	1.5	
4	75.43	68.69	1	1.5	
5	74.50	70.52	1	1.5	
6	87.18	76.08	1	1.5	
7	96.86	72.92	1	1.5	
8	86.30	72.86	1	1.5	
9	85.14	71.75	1	1.5	
10	83.37	74.37	1	1.5	
11	87.58	73.21	1	1.5	
12	84.90	70.90	1	1.5	
13	99.54	74.20	2	1.5	
14	93.28	71.44	2	1.5	

15	93.98	78.32	2	1.5	
16	84.75	76.24	2	1.5	
17	76.05	71.11	2	1.5	
18	97.74	73.61	2	1.5	
19	84.48	69.54	2	1.5	
20	71.07	73.19	2	1.5	
21	84.95	73.27	2	1.5	
22	74.46	74.10	2	1.5	
23	80.47	74.00	2	1.5	
24	72.64	73.48	2	1.5	
25	113.36	73.09	3	1.5	
26	105.98	76.50	3	1.5	
27	113.80	73.24	3	1.5	
28	120.28	74.52	3	1.5	
29	99.41	71.59	3	1.5	
30	112.11	74.25	3	1.5	
31	132.56	75.15	3	1.5	
32	126.13	74.04	3	1.5	
33	136.62	77.63	3	1.5	
34	111.83	75.69	3	1.5	
35	124.85	74.76	3	1.5	
36	128.83	75.65	3	1.5	
37	64.30	74.08	4	1.5	
38	69.76	72.96	4	1.5	
39	66.43	73.09	4	1.5	
40	74.84	78.16	4	1.5	
41	71.12	73.40	4	1.5	
42	67.86	72.43	4	1.5	
43	71.62	72.70	4	1.5	
44	57.20	71.03	4	1.5	
45	61.67	74.01	4	1.5	
46	61.50	74.30	4	1.5	
47	68.34	72.00	4	1.5	
48	78.30	72.93	4	1.5	
1	83.01	71.90	1	2	
2	79.80	70.69	1	2	
3	82.62	73.09	1	2	
4	74.69	68.01	1	2	
5	75.38	71.36	1	2	
6	85.82	74.89	1	2	
7	95.71	72.06	1	2	
8	84.81	71.60	1	2	
9	82.49	69.52	1	2	
10	81.85	73.01	1	2	
11	85.69	71.63	1	2	
12	84.53	70.59	1	2	
13	97.60	72.75	2	2	

14	90.73	69.48	2	2	
15	92.35	76.95	2	2	
16	84.02	75.58	2	2	
17	75.15	70.27	2	2	
18	95.68	72.06	2	2	
19	83.65	68.86	2	2	
20	69.74	71.81	2	2	
21	83.45	71.98	2	2	
22	73.14	72.79	2	2	
23	79.08	72.72	2	2	
24	71.79	72.62	2	2	
25	111.52	71.91	3	2	
26	103.23	74.51	3	2	
27	111.69	71.89	3	2	
28	118.58	73.47	3	2	
29	97.81	70.43	3	2	
30	109.39	72.44	3	2	
31	129.76	73.57	3	2	
32	123.57	72.54	3	2	
33	134.90	76.65	3	2	
34	109.85	74.35	3	2	
35	123.18	73.76	3	2	
36	126.91	74.53	3	2	
37	62.04	71.48	4	2	
38	67.12	70.21	4	2	
39	64.99	71.51	4	2	
40	73.64	76.91	4	2	
41	69.11	71.32	4	2	
42	66.41	70.89	4	2	
43	69.93	70.99	4	2	
44	54.53	67.71	4	2	
45	60.66	72.79	4	2	
46	60.16	72.68	4	2	
47	67.47	71.08	4	2	
48	77.87	72.53	4	2	
1	77.69	67.29	1	4	
2	76.03	67.34	1	4	
3	75.60	66.89	1	4	
4	70.09	63.82	1	4	
5	70.24	66.50	1	4	
6	81.04	70.72	1	4	
7	89.32	67.25	1	4	
8	79.86	67.43	1	4	
9	78.07	65.80	1	4	
10	77.60	69.22	1	4	
11	78.79	65.87	1	4	
12	78.45	65.51	1	4	

13	92.99	69.32	2	4	
14	85.95	65.83	2	4	
15	93.73	78.11	2	4	
16	81.08	72.93	2	4	
17	70.19	65.63	2	4	
18	92.62	69.75	2	4	
19	78.67	64.77	2	4	
20	66.59	68.57	2	4	
21	78.62	67.81	2	4	
22	69.57	69.24	2	4	
23	72.94	67.07	2	4	
24	66.88	67.65	2	4	
25	105.29	67.89	3	4	
26	94.06	67.89	3	4	
27	104.17	67.04	3	4	
28	114.53	70.95	3	4	
29	90.29	65.02	3	4	
30	102.70	68.02	3	4	
31	123.05	69.76	3	4	
32	116.12	68.16	3	4	
33	126.68	71.98	3	4	
34	104.74	70.89	3	4	
35	116.37	69.68	3	4	
36	117.63	69.08	3	4	
37	55.85	64.34	4	4	
38	59.19	61.91	4	4	
39	61.20	67.33	4	4	
40	68.98	72.03	4	4	
41	62.22	64.22	4	4	
42	61.51	65.65	4	4	
43	64.65	65.63	4	4	
44	47.25	58.67	4	4	
45	56.92	68.30	4	4	
46	56.21	67.91	4	4	
47	61.91	65.22	4	4	
48	71.60	66.69	4	4	
1	57.86	50.11	1	8	
2	49.83	44.14	1	8	
3	70.65	62.50	1	8	
4	65.90	60.01	1	8	
5	62.50	59.16	1	8	
6	70.77	61.76	1	8	
7	82.40	62.03	1	8	
8	75.89	64.08	1	8	
9	72.97	61.49	1	8	
10	77.55	69.18	1	8	
11	69.38	58.00	1	8	

12	72.87	60.85	1	8	
13	72.14	53.78	2	8	
14	65.63	50.27	2	8	
15	88.39	73.66	2	8	
16	73.21	65.86	2	8	
17	67.15	62.79	2	8	
18	86.94	65.47	2	8	
19	77.97	64.19	2	8	
20	63.86	65.75	2	8	
21	75.59	65.20	2	8	
22	58.15	57.87	2	8	
23	66.12	60.80	2	8	
24	58.49	59.16	2	8	
25	82.50	53.20	3	8	
26	87.40	63.09	3	8	
27	99.42	63.99	3	8	
28	102.92	63.76	3	8	
29	85.34	61.45	3	8	
30	92.48	61.25	3	8	
31	115.22	65.32	3	8	
32	109.91	64.52	3	8	
33	119.38	67.83	3	8	
34	98.44	66.63	3	8	
35	109.74	65.71	3	8	
36	108.56	63.75	3	8	
37	50.78	58.50	4	8	
38	54.28	56.78	4	8	
39	50.73	55.81	4	8	
40	59.18	61.80	4	8	
41	57.55	59.40	4	8	
42	56.25	60.04	4	8	
43	59.42	60.32	4	8	
44	43.35	53.83	4	8	
45	52.51	63.02	4	8	
46	52.14	62.99	4	8	
47	53.60	56.48	4	8	
48	65.53	61.04	4	8	
1	54.52	47.22	1	16	
2	50.23	44.50	1	16	
3	66.50	58.83	1	16	
4	56.30	51.27	1	16	
5	53.65	50.79	1	16	
6	62.08	54.18	1	16	
7	74.37	55.99	1	16	
8	69.23	58.45	1	16	
9	67.51	56.90	1	16	
10	67.49	60.21	1	16	

11	64.93	54.28	1	16	
12	62.67	52.34	1	16	
13	65.28	48.66	2	16	
14	60.77	46.54	2	16	
15	69.14	57.62	2	16	
16	62.35	56.09	2	16	
17	57.80	54.05	2	16	
18	76.66	57.74	2	16	
19	67.02	55.17	2	16	
20	56.84	58.53	2	16	
21	69.80	60.20	2	16	
22	47.32	47.09	2	16	
23	58.57	53.86	2	16	
24	57.22	57.88	2	16	
25	74.82	48.25	3	16	
26	85.09	61.42	3	16	
27	91.21	58.70	3	16	
28	86.92	53.85	3	16	
29	76.79	55.30	3	16	
30	82.13	54.40	3	16	
31	107.28	60.82	3	16	
32	99.97	58.68	3	16	
33	110.30	62.67	3	16	
34	91.64	62.02	3	16	
35	101.42	60.73	3	16	
36	92.00	54.02	3	16	
37	39.93	46.01	4	16	
38	49.34	51.61	4	16	
39	30.07	33.08	4	16	
40	0.00	0.00	4	16	14
41	0.00	0.00	4	16	14
42	43.68	46.62	4	16	
43	48.96	49.70	4	16	
44	27.58	34.24	4	16	
45	42.96	51.55	4	16	
46	46.48	56.15	4	16	
47	0.00	0.00	4	16	15
48	0.00	0.00	4	16	13
1	50.94	44.12	1	24	
2	44.75	39.64	1	24	
3	59.92	53.01	1	24	
4	50.45	45.94	1	24	
5	45.61	43.18	1	24	
6	45.06	39.32	1	24	
7	69.12	52.04	1	24	
8	64.91	54.81	1	24	
9	61.55	51.87	1	24	

10	62.89	56.10	1	24	
11	56.93	47.59	1	24	
12	0.00	0.00	1	24	20.5
13	62.03	46.24	2	24	
14	56.43	43.22	2	24	
15	55.22	46.01	2	24	
16	0.00	0.00	2	24	23
17	0.00	0.00	2	24	22.5
18	64.66	48.70	2	24	
19	60.60	49.89	2	24	
20	55.48	57.13	2	24	
21	65.84	56.79	2	24	
22	45.27	45.05	2	24	
23	0.00	0.00	2	24	22.5
24	49.30	49.87	2	24	
25	71.04	45.81	3	24	
26	77.16	55.70	3	24	
27	83.67	53.85	3	24	
28	78.86	48.86	3	24	
29	68.79	49.54	3	24	
30	72.23	47.84	3	24	
31	100.67	57.07	3	24	
32	93.75	55.03	3	24	
33	103.69	58.92	3	24	
34	86.30	58.41	3	24	
35	96.84	57.99	3	24	
36	0.00	0.00	3	24	23.5
37	0.00	0.00	4	24	17
38	0.00	0.00	4	24	19
39	0.00	0.00	4	24	16.5
40	0.00	0.00	4	24	14
41	0.00	0.00	4	24	14
42	0.00	0.00	4	24	17.5
43	0.00	0.00	4	24	19.5
44	0.00	0.00	4	24	18
45	0.00	0.00	4	24	22.5
46	34.00	41.07	4	24	
47	0.00	0.00	4	24	15
48	0.00	0.00	4	24	13

Appendix 5 - Multiple Comparison Statistical Analysis Study #2

Dependent Variable: PERCENT
Bonferroni
1=American Orthodontics
2=Ortho Organizers
3=GAC
4=Masel

			Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
Time(hr)	(I) BRAND	(J) BRAND				Lower Bound	Upper Bound
.00	1	2	.00000	.00000	1.000	.	.
		3	.00000	.00000	1.000	.	.
		4	.00000	.00000	1.000	.	.
	2	1	.00000	.00000	1.000	.	.
		3	.00000	.00000	1.000	.	.
		4	.00000	.00000	1.000	.	.
	3	1	.00000	.00000	1.000	.	.
		2	.00000	.00000	1.000	.	.
		4	.00000	.00000	1.000	.	.
	4	1	.00000	.00000	1.000	.	.
		2	.00000	.00000	1.000	.	.
		3	.00000	.00000	1.000	.	.
.50	1	2	-.10163	.68706	1.000	-1.99984	1.79658
		3	-1.17044	.68706	.573	-3.06865	.72777
		4	-.75306	.68706	1.000	-2.65127	1.14515
	2	1	.10163	.68706	1.000	-1.79658	1.99984
		3	-1.06880	.68706	.762	-2.96701	.82941
		4	-.65143	.68706	1.000	-2.54964	1.24678
	3	1	1.17044	.68706	.573	-.72777	3.06865
		2	1.06880	.68706	.762	-.82941	2.96701
		4	.41737	.68706	1.000	-1.48084	2.31558
	4	1	.75306	.68706	1.000	-1.14515	2.65127
		2	.65143	.68706	1.000	-1.24678	2.54964
		3	-.41737	.68706	1.000	-2.31558	1.48084
1.00	1	2	-.71715	.71487	1.000	-2.69220	1.25790
		3	-1.70114	.71487	.130	-3.67619	.27391
		4	-.76398	.71487	1.000	-2.73903	1.21107
	2	1	.71715	.71487	1.000	-1.25790	2.69220
		3	-.98399	.71487	1.000	-2.95904	.99106
		4	-4.68317E-02	.71487	1.000	-2.02188	1.92822
	3	1	1.70114	.71487	.130	-.27391	3.67619
		2	.98399	.71487	1.000	-.99106	2.95904
		4	.93716	.71487	1.000	-1.03789	2.91221
	4	1	.76398	.71487	1.000	-1.21107	2.73903
		2	4.6832E-02	.71487	1.000	-1.92822	2.02188
		3	-.93716	.71487	1.000	-2.91221	1.03789
1.50	1	2	-.82838	.79398	1.000	-3.02199	1.36523
		3	-1.96223	.79398	.104	-4.15584	.23138

		4	-.71135	.79398	1.000	-2.90495	1.48226
	2	1	.82838	.79398	1.000	-1.36523	3.02199
		3	-1.13385	.79398	.962	-3.32746	1.05976
		4	.11703	.79398	1.000	-2.07658	2.31064
	3	1	1.96223	.79398	.104	-.23138	4.15584
		2	1.13385	.79398	.962	-1.05976	3.32746
		4	1.25088	.79398	.734	-.94273	3.44449
	4	1	.71135	.79398	1.000	-1.48226	2.90495
		2	-.11703	.79398	1.000	-2.31064	2.07658
		3	-1.25088	.79398	.734	-3.44449	.94273
2.00	1	2	-.79368	.80422	1.000	-3.01560	1.42824
		3	-1.80622	.80422	.179	-4.02814	.41570
		4	-.14516	.80422	1.000	-2.36708	2.07676
	2	1	.79368	.80422	1.000	-1.42824	3.01560
		3	-1.01254	.80422	1.000	-3.23446	1.20938
		4	.64852	.80422	1.000	-1.57340	2.87044
	3	1	1.80622	.80422	.179	-.41570	4.02814
		2	1.01254	.80422	1.000	-1.20938	3.23446
		4	1.66106	.80422	.269	-.56086	3.88298
	4	1	.14516	.80422	1.000	-2.07676	2.36708
		2	-.64852	.80422	1.000	-2.87044	1.57340
		3	-1.66106	.80422	.269	-3.88298	.56086
4.00	1	2	-1.91982	1.14200	.599	-5.07497	1.23533
		3	-1.89415	1.14200	.626	-5.04930	1.26100
		4	1.31061	1.14200	1.000	-1.84454	4.46576
	2	1	1.91982	1.14200	.599	-1.23533	5.07497
		3	2.5670E-02	1.14200	1.000	-3.12948	3.18082
		4	3.23043	1.14200	.042	7.5285E-02	6.38558
	3	1	1.89415	1.14200	.626	-1.26100	5.04930
		2	-2.56701E-02	1.14200	1.000	-3.18082	3.12948
		4	3.20476	1.14200	.045	4.9615E-02	6.35991
	4	1	-1.31061	1.14200	1.000	-4.46576	1.84454
		2	-3.23043	1.14200	.042	-6.38558	-7.52852E-02
		3	-3.20476	1.14200	.045	-6.35991	-4.96152E-02
8.00	1	2	-2.62358	2.07848	1.000	-8.36602	3.11887
		3	-3.93097	2.07848	.391	-9.67342	1.81147
		4	.27726	2.07848	1.000	-5.46518	6.01971
	2	1	2.62358	2.07848	1.000	-3.11887	8.36602
		3	-1.30740	2.07848	1.000	-7.04984	4.43505
		4	2.90084	2.07848	1.000	-2.84161	8.64328
	3	1	3.93097	2.07848	.391	-1.81147	9.67342
		2	1.30740	2.07848	1.000	-4.43505	7.04984
		4	4.20823	2.07848	.294	-1.53421	9.95068
	4	1	-.27726	2.07848	1.000	-6.01971	5.46518
		2	-2.90084	2.07848	1.000	-8.64328	2.84161
		3	-4.20823	2.07848	.294	-9.95068	1.53421
16.00	1	2	-.70700	5.09582	1.000	-14.78581	13.37180
		3	-3.82648	5.09582	1.000	-17.90528	10.25233
		4	22.99852	5.09582	.000	8.91972	37.07733
	2	1	.70700	5.09582	1.000	-13.37180	14.78581
		3	-3.11948	5.09582	1.000	-17.19828	10.95933
		4	23.70553	5.09582	.000	9.62672	37.78433
	3	1	3.82648	5.09582	1.000	-10.25233	17.90528

		2	3.11948	5.09582	1.000	-10.95933	17.19828
		4	26.82500	5.09582	.000	12.74620	40.90381
	4	1	-22.99852	5.09582	.000	-37.07733	-8.91972
		2	-23.70553	5.09582	.000	-37.78433	-9.62672
		3	-26.82500	5.09582	.000	-40.90381	-12.74620
24.00	1	2	7.05969	6.88221	1.000	-11.95458	26.07395
		3	-5.11586	6.88221	1.000	-24.13013	13.89840
		4	40.54593	6.88221	.000	21.53166	59.56019
	2	1	-7.05969	6.88221	1.000	-26.07395	11.95458
		3	-12.17555	6.88221	.503	-31.18981	6.83871
		4	33.48624	6.88221	.000	14.47198	52.50050
	3	1	5.11586	6.88221	1.000	-13.89840	24.13013
		2	12.17555	6.88221	.503	-6.83871	31.18981
		4	45.66179	6.88221	.000	26.64753	64.67605
	4	1	-40.54593	6.88221	.000	-59.56019	-21.53166
		2	-33.48624	6.88221	.000	-52.50050	-14.47198
		3	-45.66179	6.88221	.000	-64.67605	-26.64753

* The mean difference is significant at the .05 level.

a Range values cannot be computed.

Appendix 6 - Elastic Dimension Error Analysis Data

Elastic #	Height	Width	lumen	Measure #
1	1.41	0.8	6.32	1
1	1.5	0.81	6.15	1
1	1.31	0.84		1
1	1.52	0.82		1
2	1.7	0.91	7.11	1
2	1.79	1.02	5.17	1
2	1.57	0.98		1
2	1.67	0.94		1
3	1.85	1.1	6.86	1
3	1.95	1.03	5.73	1
3	1.88	0.91		1
3	1.8	0.96		1
4	2.1	1.06	7.25	1
4	2.07	0.92	5.07	1
4	2.05	0.96		1
4	2.06	0.97		1
5	1.23	0.75	5.54	1
5	1.2	0.76	5.64	1
5	1.12	0.88		1
5	1.28	0.79		1
1	1.48	0.79	6.21	2
1	1.39	0.89	6.29	2
1	1.42	0.97		2
1	1.32	0.81		2

2	1.72	0.92	7.16	2
2	1.75	1.04	5.18	2
2	1.65	0.84		2
2	1.61	0.99		2
3	1.83	0.96	6.89	2
3	1.69	0.98	5.78	2
3	1.89	0.97		2
3	1.86	0.95		2
4	2.16	0.96	7.31	2
4	2.06	0.95	4.96	2
4	2.15	0.9		2
4	2.33	0.95		2
5	1.21	0.81	5.42	2
5	1.21	0.84	5.5	2
5	1.19	0.8		2
5	1.19	0.82		2

Appendix 7 - Dimension Measurement Error Statistics

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	HIGHT1 - HIGHT2	-2.50E-03	.1153	2.579E-02	-5.65E-02	5.148E-02	-.097	19	.924
Pair 2	WIDTH1 - WIDTH2	3.500E-03	7.393E-02	1.653E-02	-3.11E-02	3.810E-02	.212	19	.835
Pair 3	LUMEN1 - LUMEN2	1.400E-02	9.743E-02	3.081E-02	-5.57E-02	3.370E-02	.454	9	.660

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	HIGHT1 & HIGHT2	20	.946	.000
Pair 2	WIDTH1 & WIDTH2	20	.692	.001
Pair 3	LUMEN1 & LUMEN2	10	.995	.000

Appendix 8 - Elastic Dimension Data Grouped

Elastic #	Brandmat	Height	Width	Lumen	X section
1	1	1.3275	0.92	6.2125	1.2213
2	1	1.335	0.9775	6.065	1.304963
3	1	1.22	0.97	6.23	1.1834
4	1	1.215	0.965	6.1025	1.172475
5	1	1.3925	0.9075	6.295	1.263694
6	1	1.404	0.994	6.124	1.395576
7	1	1.3	0.85	6.05	1.105
8	1	1.3875	0.9025	6.235	1.252219
9	1	1.3625	0.8625	6.21	1.175156
10	1	1.3475	0.86	6.275	1.15885
11	1	1.3775	0.9675	6.285	1.332731
12	1	1.3575	0.8975	6.355	1.218356
13	2	1.72	1.04	6.0225	1.7888
14	2	1.5775	1.0325	6.24	1.628769
15	2	1.695	0.975	6.125	1.652625
16	2	1.775	1.0125	6.01	1.797188
17	2	1.75	1.0425	6.335	1.824375
18	2	1.71	1.045	6.165	1.78695
19	2	1.64	0.9275	6.15	1.5211
20	2	1.79	1.01	6.005	1.8079
21	2	1.665	1.06	6.19	1.7649
22	2	1.7525	0.97	6.185	1.699925
23	2	1.6725	0.9875	6.165	1.651594
24	2	1.635	1.04	6.315	1.7004
25	3	1.8375	1.0175	6.145	1.869656
26	3	1.74	1.045	6.095	1.8183
27	3	1.715	0.995	6.245	1.706425
28	3	1.8275	0.945	6.245	1.726988
29	3	1.76	0.9875	6.205	1.738
30	3	1.8825	0.98	6.12	1.84485
31	3	1.8225	0.97	6.105	1.767825
32	3	1.625	0.885	6.35	1.438125
33	3	1.75	0.915	6.2	1.60125
34	3	1.8725	0.91	6.15	1.703975
35	3	1.8525	0.9575	6.27	1.773769
36	3	1.795	0.97	6.345	1.74115
37	4	2.4225	1.13	6.055	2.737425
38	4	2.1	1.13	5.94	2.373
39	4	2.3475	1.075	5.87	2.523563
40	4	2.34	1.08	5.985	2.5272
41	4	2.27	1.0875	5.95	2.468625
42	4	2.32	1.01	6.05	2.3432

1=American L
2=American NL
3=Ortho organizers
4=GAC
5=Masel

43	4	2.1425	0.9775	6.13	2.094294
44	4	2.1975	0.945	5.91	2.076638
45	4	2.21	1.01	5.985	2.2321
46	4	2.1075	1.01	5.805	2.128575
47	4	2.2925	0.975	6.08	2.235188
48	4	2.245	0.995	6.11	2.233775
49	5	1.2425	0.83	5.5	1.031275
50	5	1.1625	0.8075	5.59	0.938719
51	5	1.0775	0.8725	5.73	0.940119
52	5	1.24	0.815	5.665	1.0106
53	5	1.05	0.8475	5.6	0.889875
54	5	1.24	0.815	5.525	1.0106
55	5	1.155	0.8175	5.705	0.944213
56	5	1.1125	0.865	5.675	0.962313
57	5	1.1975	0.8575	5.635	1.026856
58	5	1.0925	0.875	5.555	0.955938
59	5	1.305	0.8125	5.79	1.060313
60	5	1.05	0.8375	5.66	0.879375